DOCKET

SUPREME COURT
OF THE UNITED STATES

No. 09-152
Title: Russell Bruesewitz, et al., Petitioners
v.
Wyeth, Inc., fka Wyeth Laboratories, et al.
Docketed: August 6, 2009
Lower Ct: United States Court of Appeals for the Third Circuit
Case Nos.: (07-3794)
Decision Date: March 27, 2009
Rehearing Denied: May 6, 2009
Questions Presented

~~Date~~~	~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~~
Aug 4 2009	Petition for a writ of certiorari filed. (Response due September 8, 2009)
Sep 2 2009	Order extending time to file response to petition to and including October 7, 2009.
Sep 8 2009	Brief amici curiae of National Vaccine Information Center, et al. filed.
Oct 7 2009	Brief of respondents Wyeth, Inc., fka Wyeth Laboratories, et al. in opposition filed.
Oct 20 2009	Reply of petitioners Russell Bruesewitz, et al. filed.
Oct 21 2009	DISTRIBUTED for Conference of November 6, 2009.
Feb 12 2010	Supplemental brief of petitioners filed. (Distributed)
Feb 17 2010	DISTRIBUTED for Conference of March 5, 2010.
Mar 8 2010	Petition GRANTED. The Chief Justice took no part in the consideration or decision of this petition.
Apr 8 2010	The time within which to file the joint appendix and petitioners' brief on the merits is extended to and including May 24, 2010.
Apr 8 2010	The time within which to file respondents' brief on the merits is extended to and including July 23, 2010.
May 18 2010	Consent to the filing of amicus curiae briefs in support of either party or neither party received from counsel for the petitioners.
May 18 2010	Consent to the filing of amicus curiae briefs in support of either party or neither party received from counsel for the respondents.
May 24 2010	Joint appendix filed. (Statement of costs filed) REPRINTED
May 24 2010	Brief of petitioners Russell Bruesewitz, et al. filed.
Jun 1 2010	Brief amici curiae of Vaccine Injured Petitioners Bar Association, et al. filed.
Jun 1 2010	Brief amici curiae of National Vaccine Information Center, et al. filed.

Jun 1 2010	Brief amici curiae of Kenneth W. Starr and Erwin Chemerinsky filed.
Jun 1 2010	Brief amicus curiae of Marguerite Willner filed.
Jun 1 2010	Brief amici curiae of American Association for Justice, et al. filed.
Jun 1 2010	Brief amicus curiae of Mark A. Geistfeld filed.
Jul 23 2010	Brief of respondent Wyeth, Inc., fka Wyeth Laboratories filed.
Jul 29 2010	CIRCULATED.
Jul 30 2010	Brief amicus curiae of Chamber of Commerce of the United States filed. (Distributed).
Jul 30 2010	Brief amici curiae of American Academy of Pediatrics, et al. filed. (Distributed).
Jul 30 2010	Brief amicus curiae of the United States filed. (Distributed).
Jul 30 2010	Brief amici curiae of Glaxosmithkline LLC, et al. filed. (Distributed).
Jul 30 2010	Brief amicus curiae of Washington Legal Foundation filed. (Distributed).
Jul 30 2010	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
Jul 30 2010	Brief amici curiae of Patricia A. Buffler, et al. filed. (Distributed)
Aug 9 2010	SET FOR ARGUMENT ON Tuesday, October 12, 2010.
Aug 23 2010	Reply of petitioners Russell Bruesewitz, et al. filed. (Distributed)
Sep 3 2010	Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED. Justice Kagan took no part in the consideration or decision of this motion.
Sep 7 2010	Justice Kagan is recused in this case.
Sep 22 2010	Record received from U.S.D.C. for Eastern District of Pennsylvania (Philadelphia) (1 box)
Sep 28 2010	Record for U.S.C.A. for 3rd Circuit is electronic.
Oct 12 2010	Argued. For petitioners: David C. Frederick, Washington, D. C. For respondents: Kathleen M. Sullivan, New York, N. Y.; and Benjamin J. Horwich, Assistant to the Solicitor General, Department of Justice, Washington, D. C. (for United States, amici curiae.)
Oct 15 2010	Letter from counsel for the petitioners received. (Distributed)

PETITION FOR WRIT OF CERTIORARI

Supreme Court, U.S.
FILED
AUG 4 - 2009
OFFICE OF THE CLERK

No. 09-152

In the Supreme Court of the United States

RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES AND LEDERLE LABORATORIES,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR A WRIT OF CERTIORARI

Collyn A. Peddie
Counsel of Record for Petitioners
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway, Suite 600
Houston, Texas
(713) 230-2200

LEGAL PRINTERS LLC, Washington DC • 202-747-2400 • legalprinters.com

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 ["the Act"] expressly preempts certain design defect claims against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). A-104.

The Question Presented is

Whether the Third Circuit erred in holding that, contrary to its plain text and the decisions of this Court and others, Section 22(b)(1) preempts all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not?[1]

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[1] Whether Section 22(b)(1) of the Act encompasses both negligent and strict liability design defect claims is not at issue in this petition. Both the *Ferrari* court and the court below found that it encompasses both claims. *See* A-35; *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 242 (Ga. 2008).

RULE 14(b) STATEMENT

All parties to the proceedings in the United States Court of Appeals for the Third Circuit are listed in the caption.

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The opinion of the United States District Court for the Eastern District of Pennsylvania, August 24, 2007, is reported at 508 F. Supp. 2d 430 (E.D. Pa. 2007). It is reproduced at A-53-100.

JURISDICTION

This Court has jurisdiction to review the final judgment of the U.S. Court of Appeals for the Third Circuit, entered March 27, 2009, under 28 U.S.C. § 1254(1). A-1. A petition for panel rehearing and rehearing *en banc* was timely filed. The Third Circuit denied both motions on May 6, 2009. A-101. This petition is timely under 28 U.S.C. § 2101(c) and Supreme Court Rules 13.1 and 13.3 because it is being filed within 90 days of the date the Third Circuit denied rehearing.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the following constitutional and statutory provisions: The Supremacy Clause of the United States Constitution, art. VI, § 1, cl. 2; and 42 U.S.C. § 300aa-22, *et seq.* These provisions are reproduced at A-103-06.

INTRODUCTION

Responding to the pleas of parents of children catastrophically injured by vaccines, Congress passed the National Childhood Vaccine Injury Act which established a no-fault compensation program to streamline awards to vaccine-injured children. *See Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995). This administrative program does not and was never intended to provide an exclusive remedy for vaccine-related injuries. To the contrary, the Act expressly preserves state-law tort remedies 1) to insure parents' rights to seek compensation when it is not available under the program or is unsatisfactory; and 2) to retain vaccine manufacturers' incentives to improve the safety of their vaccines because the Act would otherwise shift all financial responsibility for vaccine-related injuries to parents and taxpayers.[2]

"The Act additionally helps manufacturers by providing certain federal modifications of state tort law. For example, it forbids the award of compensation for injuries that flow from 'unavoidable side effects.'" *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.). Thus, Section 22(b)(1) provides that "no manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable . . ." 42 U.S.C. § 300aa-22(b)(1). A-104.

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[2]The Act's compensation program is funded through an excise tax on each dose of vaccine. *See* 26 U.S.C. § 4131.

The Third Circuit's interpretation of Section 22(b)(1) as preempting all vaccine design defect claims, whether side effects were unavoidable or not, renders its plain text a nullity. Worse, the Court's construction is grounded in three largely discredited notions: 1) that the Act provides an exclusive remedy, not an affirmative defense, for design defect claims; 2) that the alleged comprehensiveness of the U.S. Food and Drug Administration ["FDA"] approval process impliedly preempts vaccine design defect claims and renders the side effects of approved vaccines "unavoidable" as a matter of law; and 3) that Congress did not intend that there be any difference in the legal treatment of vaccines and other prescription drugs.

There are, therefore, three reasons why this Court should grant *certiorari*. First, there is a deep, direct, and mature conflict on the question presented between the unanimous Supreme Court of Georgia in *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (2008) and the Third Circuit here. As a result of this split in authority, after exhausting administrative remedies in the vaccine program, children in Georgia who are injured by vaccines may bring design defect claims against vaccine manufacturers when the use of safer alternative vaccines could have avoided their injuries. By contrast, Hannah Bruesewitz and children like her in the Third Circuit and elsewhere may be precluded from pursuing identical design defect claims even when the same safer alternative vaccines could have avoided their suffering too. This intolerable disparity in treatment under the same federal statute is not only tragically unfair; it may have constitutional dimensions as well.

Second, the question presented is a critically important and recurring one requiring resolution by this Court. By holding all vaccine design defect claims preempted, the Third Circuit robs seriously-injured children and their parents of their right to seek compensation under state tort law when safer alternative vaccines would have prevented their injuries. Moreover, so long as the question presented remains unresolved, it will recur and courts will be forced to use scarce judicial resources to decide it. Most important, resolution now is essential because, by immunizing an entire industry from responsibility for the continuing safety of its products, the Third Circuit has disrupted a stable vaccine supply for all children, stifling innovation and removing incentives for manufacturers to develop and market safer vaccines.

Finally, *certiorari* is warranted because the Third Circuit grievously misinterprets Section 22 to preempt all vaccine design defect claims. Using questionable statutory construction principles, the Court improperly ignores Section 22(b)(1)'s conditional language, provisions expressly preserving tort claims, and Section 22(e), which expressly preempts state laws that would ***prevent*** the pursuit of state-law tort claims the Act itself does not preclude. The Court then expands improperly the scope of Section 22(b)(1)'s preemption clause to create an exclusive remedy in defiance of this Court's recent preemption decisions, those of courts around the country, the presumption against preemption, and the clearly expressed intent of Congress. And it does so even though the FDA itself, when specifically asked to opine on preemption in this case, neither considered such claims preempted nor asked that the trial court so hold. A-107-09; A-113.

STATEMENT OF THE CASE

Within hours after receiving the diphtheria, tetanus, and pertussis ["DTP"][3] vaccine manufactured by Respondents,[4] Hannah Bruesewitz, then a healthy six-month old, suffered catastrophic injuries and the first of a lifetime of agonizing seizures. A-6; 57. As a result of receiving Respondents' vaccine, Hannah, a teenager now, suffers from residual seizure disorder and remains profoundly developmentally impaired. A-6. She will need lifetime supervision and care. *Id.*

In 1995, Hannah and her parents began their long journey through the courts and administrative agencies, seeking "simple justice"[5] and compensation for her vaccine-related injuries. In 14 years, she has received neither. Whether her journey ends in the Third Circuit depends upon this Court's decision on her Petition for Writ of *Certiorari*.

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[3]Although the references are interchangeable, the Department of Health and Human Services ["HHS"] and the Health Resources and Service Administration ["HRSA"] use the acronym "DTP" rather than the more commonly used "DPT." *See* http://www.hrsa.gov/vaccinecompensation/covered_vaccines.htm.

[4]Wyeth, Inc., f/k/a Wyeth Laboratories, Wyeth-Ayerst Laboratories, Wyeth-Lederle Vaccines, and Lederle Laboratories [hereafter "Wyeth" or "Respondents"].

[5]In describing the purposes of the Act at the time of its passage, Dr. Martin Smith, Chairman, American Association of Pediatrics, assured parents it would provide "simple justice to children." *See Compensating Vaccine Injuries: Are Reforms Needed?: Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources,* 106th Cong. (1999) (statement of Barbara Lou Fisher).

DTP Vaccines

Vaccines stimulate the production of antibodies that protect against disease. *Toner v. Lederle Labs., Div. of American Cyanamid Co.*, 779 F.2d 1429, 1430 (9th Cir. 1986). Some infectious organisms, including those causing diphtheria and tetanus, excrete insolable toxins. *Id.* When a toxin is inactivated, it is transformed into a toxoid. The toxoid is then used in a vaccine to immunize against disease by stimulating the production of antibodies in the recipient, even though it has lost its own poisonous qualities. *Id.*

This is not the case with Tri-Immunol, the vaccine manufactured by Respondents and administered to Hannah Bruesewitz. Tri-Immunol, which was licensed for production sixty years ago, A-58, is a "whole cell" vaccine because it contains whole killed pertussis organisms. *Toner,* 779 F2d at 1430. The whole organism was used because it contains many different antigens, and, initially, scientists had not isolated the one that stimulates protection against the disease. *Id.*

The whole cell pertussis vaccine, however, is neurotoxic and can cause both local and severe adverse reactions. *Id.* Severe reactions include encephalopathy, paralysis, and even death. *Id.* at 1430-31. The whole-cell vaccine, however, leaves no "footprint" evidencing that it was the catalyst for even the most severe injury.[6]

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[6]*See Andreu v. Sec'y of HHS*, 569 F.3d 1367, 2009 U.S. App. LEXIS 13048 *36 (Fed. Cir. June 19, 2009); Division of Health Promotion and Disease Prevention, Institute of Medicine, *DPT Vaccine & Chronic Nervous System Dysfunction: A New Analysis* (Kathleen R. Stratton, Cynthia J. Howe, and Richard B.

Because of the well-known neurotoxicity of the whole-cell vaccine, during the 1950's, the Eli Lilly Company developed a fractionated or so-called "split" cell pertussis vaccine called Tri-Solgen that was prepared by treating whole killed pertussis cells with salt. *Toner*, 779 F.2d at 1431. Early studies indicated that this method of preparation resulted in a less toxic vaccine. *Id.* Following its approval by the FDA in 1967, Tri-Solgen occupied a substantial share of the DTP market. *Id.* Nevertheless, Lilly withdrew from the vaccine business in 1975 and voluntarily requested that its license to produce Tri-Solgen be withdrawn without prejudice. *See Foyle v. Lederle Labs.*, 674 F. Supp. 530, 534 (E.D.N.C. 1987). However, it sold its right to produce Tri-Solgen to Respondent Wyeth Laboratories. *Toner*, 779 F.2d at 1431.

Rather than seek FDA approval to market the safer, split-cell vaccine, however, Respondents asked the FDA only to allow them to market ***as*** Tri-Solgen a vaccine using their own more dangerous, but cheaper, whole-cell pertussis component. It is not surprising that the FDA refused to allow such bait and switch tactics. There is no indication that Respondents ever sought to market Tri-Solgen in its safer, original formulation during the 17 years before Hannah Bruesewitz received their more dangerous vaccine.

Hannah was injured when she received the third of five recommended doses in the DTP vaccination series. A-57. At the time of Hannah's vaccination, the FDA had already approved Respondents' application to market an alternative DTP vaccine, trade-named Acel-

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Johnston, Jr., eds., 1994).

Imune, that contained an even safer, acellular pertussis component. A-58. The acellular vaccine is less reactive and causes fewer adverse events because it has been detoxified using chemical techniques. A-7. Thus, "the general consensus is that the older [whole-cell] vaccine is more dangerous than the newer [acellular] version." *Andreu*, 2009 U.S. App. LEXIS 13048 at *16.

Unfortunately, Respondents had only sought and obtained approval to market Acel-Imune for the fourth and fifth doses in Hannah's vaccination series. A-7. Respondents did not seek and obtain approval to use Acel-Imune for the first three doses until more than four years later. A-7-8. As a result, Hannah received the more dangerous whole-cell vaccine, which was not manufactured after 1998, even though safer alternatives had already been developed and marketed. A-8

The Vaccine Act

In the mid 1980's, thousands of American families faced a long, hard slog through the tort system or endless settlement negotiations with vaccine manufacturers to obtain compensation for vaccine-related injuries. Even then, "no recovery [might] be available. Yet futures have been destroyed and mounting expenses must be met." H.R. Rep. No. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347. At the same time, some vaccine manufacturers threatened to abandon this field of therapy because of the threat of lawsuits over mounting vaccine-related injuries. *See Andreu*, 2009 U.S. App. LEXIS 13048 at *12; H.R. Rep. No. 99-908, at 6.

Responding to these concerns, Congress created a no-fault administrative program that "postpones actions in state court by requiring plaintiffs to pursue remedies under the NCVIA before attempting a tort claim in state court." Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L. J. 351, 355 (2001). Under this compensation scheme, awards were to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3. In this fashion, Congress sought to"[c]reate a compensation system that is speedy and generous enough to dissuade petitioners from going into court." H.R. Rep. 100-391(I), at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365; H.R. Rep. No. 99-908, at 26 ("vaccine-injured persons will now have an appealing alternative to the tort system").

The Act was enacted in two phases and the House Energy and Commerce Committee had primary responsibility for both. In the first phase in 1986, Congress set up the structure of the vaccine compensation program; however, "the Act as passed did not include a source of payment for such compensation and made the compensation program and accompanying tort reforms contingent upon the enactment of a tax to provide funding for the compensation." H.R. Rep. No. 100-391(I), at 690; A-36. In 1987, Congress passed amendments to the Act that funded the program and rendered Section 22 effective in 1988. *Id.*

The Act provides two separate mechanisms to obtain benefits: table claims and causation in fact claims. In a table claim, a claimant who shows that he

or she received a vaccination listed in the Vaccine Injury Table within a prescribed period is afforded a presumption of causation. 42 U.S.C. §§ 300aa-11(c)(1)(C)(I), 300aa-14. "He need not prove fault. Nor, to prove causation, need he show more than that he received the vaccine and then suffered certain symptoms within a defined period of time." *Schafer*, 20 F.3d at 2 (citing §§ 300aa-13, 300aa-14).

Prior to March 10, 1995, "residual seizure disorder" following DTP vaccination was considered a table injury. *See Andreu,* 2009 U.S. App. LEXIS 13048 at *13. The disorder has accounted for approximately 40% of all claims filed in the vaccine program.[7] By the time Hannah's family filed her claim in April 1995, however, residual seizure disorder no longer qualified as a table injury. *See* 60 Fed. Reg. 7678 (Feb. 8, 1995). As a result, her family could not avail themselves of the table method of establishing causation and had to show that Hannah's seizure disorder was "caused in fact" by the DTP vaccine she received. *See Andreu,* 2009 U.S. App. LEXIS 13048 at *13.

To seek compensation for any vaccine-related injuries, victims and their families must first bring their claims in the Court of Federal Claims. *See* 42 U.S.C. § 300aa-12. If they are dissatisfied with the award obtained, receive no award, or the special master assigned to their case fails to rule within a

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[7] *See* U.S. Gen'l Accounting Office, *Vaccine Injury Compensation; Program Challenged to Settle Claims Quickly and Easily*, 14, table 6 (Washington, D.C. Dec. 1999), *available at* http://www.gao.gov/new.items/he00008.pdf. In fact, more than 80% of all compensation awarded under the Act was for DTP cases. *See* Scott, *supra*, at 353, n.19.

specified time, they may decline any award and file a tort claim. 42 U.S.C. §§ 300aa-21(a), 21(b)(1), 21(c).

In passing the Act, Congress recognized that immunizing an entire industry from tort claims and thus shifting financial responsibility for the injuries caused by its products to others could destroy incentives to make vaccines safer. *Schafer*, 20 F.3d at 3. As a result, it provided manufacturers with only limited immunity while expressly preserving state-law tort claims. *See* 42 U.S.C. §§ 300aa-22(a) (applying state law to civil action for damages for vaccine-related injuries). A-104.

To that end, Congress preempted certain design defect claims for damages only for "unavoidable" injuries. Section 22(b)(1) provides:

> (b) Unavoidable adverse side effects; warnings
>
> > (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1); A-104. To preserve incentives to innovate, Section 22(b)(1)'s conditional

phrase functions as a biologic "sunset" clause, ending the immunity from design defect claims it affords vaccine manufacturers who produce and market older, more dangerous vaccines when better alternatives become available.

For the purposes of Section 22(b)(1), the Act also defines "proper directions and warnings" and creates a rebuttable presumption addressing them in that context alone.[8] Finally, in Section 22(e), Congress sought to insure the right to file state-law claims by expressly preempting state law that would interfere with the pursuit of claims the Act itself does not prohibit.

Proceedings Below

On April 3, 1995, Hannah and her family filed a petition in the U.S. Court of Federal Claims. A-54; *Bruesewitz v. Sec'y of Dep't of HHS*, No. 95-0266V, 2002 WL 31965744, at *1 n.1 (Fed. Cl. Dec. 20, 2002). On February 14, 2003, they rejected the judgment of the Vaccine Court which had awarded them no compensation. *Id.*

Petitioners filed suit for damages in the Philadelphia County Court of Common Pleas in October, 2005. *Id.* Respondents removed the case based on diversity of citizenship, and filed their first Motion for Summary Judgment alleging that

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[8] *Id.* at § 22(b)(2). The trial court and Third Circuit incorrectly found that Section 22(b)(2) provides a free-standing presumption of adequate warnings in all vaccine cases, not the support for Section 22(b)(1) the statute's plain text clearly provides.

Petitioners' claims were preempted. Since little, if any, discovery had taken place, the court denied the motion without prejudice by Order dated February 22, 2007. *Id.*

In the mean time, the court sought an amicus brief from the FDA on the question presented. A-113. On November 9, 2006, an HHS representative responded but asserted no preemption of all design defect claims. A-107-109.

After allowing Petitioners to amend and to conduct some discovery, the court granted summary judgment based upon the prior motion and subsequent briefing. It held Petitioners' design defect claims preempted by the Act and that Petitioners had failed to raise questions of material fact on their manufacturing defect and failure-to-warn claims. A-9; A-99.

Petitioners appealed to the Third Circuit which affirmed the summary judgment. A-1-52. Petitioners sought rehearing which was denied. A-101. From the Third Circuit's decision, Petitioners seek a writ of *certiorari*.

REASONS FOR GRANTING THE PETITION

This Court should grant *certiorari* for three reasons. First, there is a deep, direct, and mature conflict on the question presented between the unanimous Supreme Court of Georgia in *Ferrari* and the Third Circuit. Second, the question presented will increasingly recur if not resolved now and is of national importance. Finally, the Third Circuit grievously misinterprets Section 22(b)(1) to provide an exclusive remedy and to preempt claims it does not, in fact, preempt.

I. THERE IS A DEEP, DIRECT, AND MATURE CONFLICT OVER THE MEANING AND SCOPE OF SECTION 22(b)(1)'S EXPRESS PREEMPTION CLAUSE

A. The Conflict is Direct and Clean

The *Ferrari* and *Bruesewitz* courts reach opposite conclusions as to the "'domain expressly pre-empted by [the] language'" of the Act. A-13 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996)). While both courts agree that Section 22(b)(1)'s express preemption language applies to both negligent and strict liability design defect claims, *see supra* note 1, they disagree over the meaning of its conditional phrase: "if the injury or death resulted from side effects that were unavoidable. . . ." 42 U.S.C. § 300aa-22(b)(1). Thus, in *Ferrari*, the unanimous Georgia Supreme Court holds that

> [S]ubsection (b)(1) clearly does not preempt all design defect claims against vaccine manufacturers, but rather

> provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case by case basis, that the particular vaccine was unavoidably unsafe.

668 S.E.2d at 393. By contrast, the Third Circuit concludes that "a 'clear and manifest' expression of congressional intent supports" an interpretation of the Act that bars all design defect claims. Thus,"plaintiffs design defect claims are expressly preempted by the Vaccine Act" whether the vaccine's side effects were unavoidable or not. A-52.

In particular, the court rejects the *Ferrari* opinion, declaring that "we do not consider the *Ferrari* court's reading [of Section 22(b)(1)] to be compelling. . . More importantly, we think the *Ferrari* court's construction is contrary to the structure of the Act. . . " A-28-29.

The Third Circuit's analysis of the question presented could not be more simple, unambiguous, dispositive, or wrong. It first reviews Section 22's first three subsections and concludes that "by reading these three provisions together, it becomes clear that Congress intended that subsections (b) and(c) should be an outright bar to ***some*** claims." A-28 (emphasis supplied). Without reviewing any legislative history, the court rejects *Ferrari*'s construction of Section 22(b)(1) as "contrary to the structure of the Act because it does not bar ***any*** design defect claims." A-29 (emphasis supplied). It expresses no doubt in doing so. Instead, it explains: "if we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect

claim is subject to evaluation by a court." A-29. Summing up, it concludes that Congress could not have intended such a situation because, in some states, it "could create an awkward dichotomy in the case law of these states – their state would be required to engage in case-by-case analysis of all strict liability and negligent design defect claims brought under the Vaccine Act, while barring strict liability design defect claims against prescription drug manufacturers." A-30.

Although it reaches its decision on the question presented easily, the Third Circuit struggles to determine whether the preemption provisions apply to both negligent and strict liability claims. In answering ***that*** question, and ***not*** the question presented, the court wrestles with legislative history, some allegedly illustrating Congress' intention to shield DTP vaccine manufacturers. A-40-42.

It has been suggested by respondents in *Ferrari* that the court's reference to this background information constitutes some sort of fact-finding that the DTP vaccine's side effects were "unavoidable" for purposes of Section 22(b)(1). It does not. First, the quoted information does not so state. Second, the court makes clear that it does not answer the question presented using legislative history. A-28-30, 40-42. Third, even if it does, such an alleged statement of Congressional intent would merely "inform interpretive choice" regarding the Act's language, not act as a free-standing, dispositive fact. *See Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 261 (2004); *Richlin Sec. Serv. Co. v. Chertoff*, 128 S.Ct. 2007, 2016 (2008).

Finally, even if Congress had found that whole-cell DTP vaccines' side effects were unavoidable and subject to immunity ***in 1986***, there is nothing in the Act or its legislative history that evinces Congress' intention to protect such manufacturers forever, even when the development of an acellular vaccine renders the whole-cell vaccine's side effects "avoidable."

B. The Conflict is Deep and Mature Enough

Even before the Act's effective date in 1988, courts began wrestling with the scope of its preemption, if any, of state-law tort claims. At least thirteen courts have decided whether the Act provides an exclusive federal remedy and thus completely preempts state tort claims against vaccine manufacturers.[9] All held that, while it may provide a preemption defense subject to case-by-case evaluation by trial courts, the

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[9] *Zatuchni v. Sec'y of HHS*, 516 F.3d 1312, 1321 n.10 (Fed. Cir. 2008); *Galindo v. Am. Home Prods.*, 2004 U.S. Dist. LEXIS 27752 *20 (S.D. Tex. Feb. 10, 2004); *Davila v. Am. Home Prods. Corp.*, 2004 U.S. Dist. LEXIS 4370 *17-18 (W.D. Tex. Feb. 3, 2004); *Shadie v. Aventis Pasteur, Inc.*, 254 F. Supp. 2d 509, 516-17 (M.D. Pa. 2003); *Bertrand v. Aventis Pasteur Labs., Inc.*, 226 F. Supp. 2d 1206, 1211 (D. Ariz. 2002); *Oxendine v. Merck & Co.*, 236 F. Supp. 2d 517, 523 n.3 (D. Md. 2002); *Mead v. Aventis Pasteur, Inc.*, 2002 U.S. Dist. LEXIS 25552 *13 (D. Or. June 7, 2002), *Doherty v. Pasteur*, 2002 U.S. Dist. LEXIS 9596 *10-12 (N.D. Cal. May 15, 2002); *Garcia v. Aventis Pasteur, Inc.*, 2002 U.S. Dist. LEXIS 15122 *11 (W.D. Wash. Apr. 22, 2002); *King v. Aventis Pasteur, Inc.*, 210 F. Supp. 2d 1201, 1207 (D. Or. 2002); *Haggerty v. Wyeth Ayerst Pharm.*, 79 F. Supp. 2d 182, 186, 189 (E.D.N.Y. 2000); *Jones v. Lederle Labs., Div. of Am. Cyanamid Co.*, 695 F. Supp. 700, 710 (E.D.N.Y. 1988); *Reilly v. Wyeth*, 870 N.E.2d 740, 752 (Ill. App. Ct. 2007).

Act does not preclude any state claim.[10] In rejecting Section 22(b)(1)'s case-by-case requirement because it concludes that the Act does ***not*** merely provide a preemption defense subject to evaluation by state courts but bars all design defect claims, the Third Circuit relied heavily upon the "complete" or field preemption principles these courts unanimously rejected.

At least fourteen other courts, including three circuits courts and two highest state courts,[11] have decided whether federal regulation of vaccines is so

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[10] *See, e.g., Shadie*, 254 F. Supp. 2d at 516 (the court explained: "[e]ssentially, they are arguing that the Vaccine Act is not an affirmative defense to the plaintiffs' claims, but rather provides for an exclusive federal remedy that precludes separate state court causes of action. . . .").

[11] *See Schafer*, 20 F.3d at 7 ("the Act's language suggests that pre-emption is not intended"); *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1988) & case cited therein; *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1113 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988); *Mazur v. Merck & Co.*, 742 F. Supp. 239, 246-47 (E.D. Pa. 1990), *aff'd on other grounds*, 964 F.2d 1348 (3d Cir. 1992); *Jones v. Lederle Labs.*, 695 F. Supp. at 712; *Foyle*, 674 F. Supp. at 534; *Martinkovic v. Wyeth Labs., Inc.*, 669 F. Supp. 212, 215 (N.D. Ill. 1987); *MacGillivray v. Lederle Labs.*, 667 F. Supp. 743, 746 n.1 (D.N.M. 1987); *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1340 (C.D. Cal. 1987) (discussing § 22(b)(1)); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1492 (D. Kan. 1987), *aff'd in part, rev'd on other grounds*, 906 F.2d 1399 (10th Cir. 1990); *Patten v. Lederle Labs.*, 655 F. Supp. 745, 749 (D. Utah 1987); *Wack v. Lederle Labs.*, 666 F. Supp. 123, 127-28 (N.D. Ohio 1987); *Koehler by Koehler v. Wyeth Lab. Div. of Am. Home Prods. Corp.*, 1987 U.S. Dist. LEXIS 16861 *6-8 (S.D. Ind. Sept. 8, 1987); *Shackil v. Lederle Labs., Div. of Am. Cyanamid, Co.*, 561 A.2d 511, 527 (N.J. 1989); *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 751 (Ohio 1988).

comprehensive as to preempt impliedly state tort claims like those asserted here. In answering "no," the vast majority of these courts relied on the Act itself as an expression of Congressional intent ***not*** to preempt broadly state tort law. In fact, many of these courts and numerous others held that the structure and purposes of the Act itself do not preempt and thus supplant civil tort remedies.[12] In fact, several courts specifically addressed the question of whether Section 22 expressly preempts state tort claims.

Before the Act became effective in 1988, the court, in *Reed v. Connaught Labs., Inc.*, 1987 Pa. Dist. & Cnty. Dec. LEXIS 79 *9 (Pa. C.P. 1987), relying Section 22 's language and legislative history, concluded "that there has been no express pre-emption of state tort remedies for vaccine-related injuries." In *Mazur v. Merck & Co.*, 742 F. Supp. 239, 246-47 (E.D. Pa. 1990), the court concurred and held that Subsections 22(a) and (e) "[c]ertainly manifest Congress's intent to preserve traditional state tort remedies for redress of injuries related to vaccine use." The Supreme Court of Nevada agreed in principle, holding that "certainly the Act contains no express language which would preempt the Allison's [strict liability] tort actions." *Allison v. Merck & Co.*, 878 P.2d 948, 961 (Nev. 1994). Thus, these decisions and those discussed above undercut the notion that the structure and purposes of Section 22 favor preempting all design defect claims. Equally important, all erode the Third Circuit's underlying assumption that the alleged comprehensiveness of the

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[12]*See Hurley*, 851 F.2d at 1536, 1539-40; *Abbot*, 844 F.2d at 1112-13; *Foyle*, 674 F. Supp. at 533; *Martinkovic*, 669 F. Supp. at 212; *Graham*, 666 F. Supp. at 1491-92; *Patten*, 655 F. Supp. at 745.

FDA approval process for vaccines would impliedly preempt all design defect claims or somehow render the side effects of all approved vaccines "unavoidable" as a matter of law.[13]

Many of these decisions involve DTP vaccines. *See, e.g.*, *Hurley*, 863 F.2d 1173; *Foyle*, 674 F. Supp. 530. In finding that claims involving such vaccines are not preempted, these opinions also address but run counter to the Third Circuit's alleged holding that Congress somehow singled out DTP claims for complete preemption. A-61-62.

In 2002, the FDA began to reverse its historic position that its regulations do not preempt state tort claims against manufacturers of prescription drugs.[14] For six years, it took a strong pro-preemption position with regard to prescription drugs generally.[15] Until late 2006, however, it did not specifically address the question of preemption of vaccine claims.

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[13] *See* Nitin Shah, *When Injury is Unavoidable: The Vaccine Act's Limited Preemption of Design Defect Claims*, at 25 (May 19, 2009), *available at* http://ssrn.com/abstract=1407343 (to be published in the University of Virginia Law Review and concluding that Section 22(b)(1) preempts only those design defect claims where the side effects are first found unavoidable).

[14] The FDA had consistently recognized that state-law claims could coexist with federal prescription drug regulation. *See* 63 Fed. Reg. 66378, 66383-84 (Dec. 1, 1998), *quoted in In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 788 (E.D. La. 2007).

[15] These efforts culminated in the issuance of a "preamble to a 2006 FDA regulation" declaring that state-law failure-to-warn claims "threaten the FDA's statutorily prescribed role. . . ." *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009).

Within this larger discussion of the scope of preemption under the Act, a critical mass of trial and appellate courts have addressed the question presented directly and generated several lines of cases. In *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 665 (S.D. Tex. 2004), *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 308 (E.D. Pa. 2007), and *Wright v. Aventis Pasteur, Inc.*, 2008 Phila. Ct. Com. Pl. LEXIS 221 *29 (2008), the courts based their conclusion that Section 22(b)(1) bars all design defect claims on the conflict preemption principles many courts have rejected, holding that case-by-case determination "could interfere with the federal government's efforts to establish a uniform national standard for childhood vaccines" and thus "undermine the FDA's authority to set [such] standards. . . ." *Blackmon*, 328 F. Supp. 2d at 665. All also relied upon, at best, ambiguous legislative history and an unduly broad reading of Restatement comment k that the court in *Ferrari* recognized as fatally flawed.[16]

Despite its ultimate holding, the court in *Sykes* allowed that a "case-by-case" interpretation of Section 22(b)(1) was as plausible as the one it adopted. 484 F. Supp. 2d at 301. Similarly, both courts in *Militrano v. Lederle Labs.*,769 N.Y.S.2d 839, 844 (N.Y. Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (N.Y. App. Div., 2006), correctly recognized that the plain language of § 22(b) "could be read as barring defective design claims only where the injury was unavoidable, with a finding of unavoidability being determined on a case-by-case basis." Nevertheless, the trial court found preemption

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[16] *See* A-82-85; *Ferrari*, 668 S.E.2d at 239-40; *Wright*, 2008 Phila. Ct. Com. Pl. LEXIS 221 at *29; RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

of all design defect claims because it concluded from selected legislative history that "Congress intended to view Comment k and the Act as immunizing vaccines from liability for design defects." 769 N. .S.2d at 845.

As discussed above, the Georgia Supreme Court and the court it affirmed in *Ferrari* reached the opposite conclusion. Unlike the previous courts to decide the question presented, the *Ferrari* courts discussed and properly applied the presumption against preemption which requires that the court "accept the reading that disfavors pre-emption . . ." *Ferrari*, 668 S.E.2d at 242. The court explained that "the long history of tort litigation against manufacturers of [prescription drugs and vaccines] adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.* (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

While the question presented has been percolating in the nation's courts for the last 20 years, Congress, the FDA and this Court have all weighed in. When specifically asked by the trial court ***in this case*** to express its opinion concerning the question presented in 2006, the FDA refused to assert that all design defect claims were expressly preempted, stating that it had no authority over such claims because "the Secretary is not a party to that civil action and does not administer the provisions, such as section 22(b), that govern such civil actions. A-107-08. Although this Court has made clear the FDA pronouncements are entitled to little or no weight, *see Levine*, 129 S. Ct. at 1204, in light of FDA's strong pro-preemption posture with regard to other prescription drugs in

2006, the FDA's refusal to assert that state tort claims interfere with its authority speaks volumes.[17]

Congress has also spoken to this issue, albeit indirectly. In 2004, it passed a law granting sole jurisdiction to federal courts over claims of injuries from any "covered countermeasure" against a pandemic or epidemics, which can include vaccines. Pub. L. No. 109-148 (2005); 42 U.S.C. §§ 247d-6d, 247d-6e. The law gives the Secretary of Health and Human Services broad authority to declare a drug or vaccine a "covered countermeasure" with attendant liability protection. *Id.* There would have been no need to make vaccines already covered by the Act subject to such legislation if Congress had already created an exclusive remedy for vaccine-related injuries.

Finally, in 2008, this Court addressed and narrowed the issues here when it reaffirmed that the presumption against preemption applies when addressing questions of express preemption, holding that "[w]hen the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors preemption.'" *Altria Group, Inc. v. Good*, 129 S.Ct. 538, 543 (2008) (quoting *Bates*, 544 U.S. at 449)). All of the appellate courts that have specifically addressed the question presented have held that a case-by-case

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[17]Since that time, the Obama Administration has set new, strongly anti-preemption policy. *See* Memorandum to Heads of Executive Departments and Agencies from Barack Obama, President, May 20, 2009, *available at* http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/.

reading of Section 22(b)(1) is plausible. The court below should have followed *Altria* and adopted that reading.

C. The Conflict Creates Intolerable Unfairness to Litigants in Different Jurisdictions

Hannah Bruesewitz will turn 18 in October 2009. She suffered catastrophic injuries as a baby in 1992. Although her care will cost $9 million over her lifetime, to date, she has received no compensation whatsoever. Instead, she and her family have spent 14 years in courts and administrative proceedings. Because she lives in Pennsylvania, she can no longer seek recompense. If her family lived in Georgia, she could.

Unless this Court resolves the conflict between the *Bruesewitz* and *Ferrari* decisions, whether families have the right to sue for their children's vaccine-related injuries will remain largely a question of geography. Following *Bruesewitz, Sykes* and *Wright* [until the Superior Court rules], Pennsylvania courts will likely bar all design defect claims, whether safer alternatives exist or not. Following *Ferrari*, courts in Georgia will allow such claims to proceed if the manufacturer can show that no safer vaccine was available. Courts in Texas, following *Blackmon,* may bar claims just as courts in New York, following *Militrano*, will. Courts and litigants in other states will have to guess whether their design defect claims are preempted. "By itself, this confusion on an important and recurring question of federal law provides sufficient reason to grant *certiorari* in this case." *Swanner v. Anchorage Equal Rights Comm'n*, 513 U.S. 979, 982 (1994) (Thomas, J., dissenting).

Moreover, this dichotomy may have constitutional dimensions. Under the equal protection clause, similarly situated individuals may not be treated differently under a federal statute solely because of the state in which they reside. *See Village of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000); *see also Golden State Transit Corp. v. Los Angeles*, 493 U.S. 103, 105 (1989) (deprivation of state right preempted by federal statute may be cognizable under 42 U.S.C. § 1983). Unless this Court resolves the question presented, this untenable geographic disparity will persist.

D. Further "Percolation" of the Question Presented Will Not Assist This Court

Because the decisions of this Court and of the other courts discussed above have narrowed and refined the issues here, there is little benefit in allowing the question presented to percolate further in the lower courts before this Court decides it. The compelling arguments raised by the court in *Ferrari* are unlikely to go away, especially since this Court has repeatedly reaffirmed the presumption against preemption on which that court relied. More than twenty courts, including four circuit courts and two highest state courts, have addressed and undercut the arguments the Third Circuit relied upon in finding all design defect claims preempted. In fact, it is unclear what further percolation would reveal, if anything. Because the marginal utility of waiting for additional courts to rule is thoroughly outweighed by the unfairness to litigants in failing to resolve the question presented, *certiorari* is warranted now.

II. THE MEANING AND SCOPE OF SECTION 22(B)(1)'S EXPRESS PREEMPTION CLAUSE IS A RECURRING QUESTION OF NATIONAL IMPORTANCE

A. The Question Presented Will Recur if Not Resolved by This Court Now

The failure of this Court to decide the question presented would waste judicial resources, those of litigants, and unduly delay the very compensation the Act was intended to speed. Defendants now file preemption motions as a matter of course in cases emerging from the vaccine program. Indeed, the question presented is pending before the Pennsylvania Superior Court in an appeal from a ruling in the thimerosal MDL. *Wright v. Aventis Pasteur, Inc.*, 2008 Phila. Ct. Com. Pl. LEXIS 221 (2008). Spurred by the opinion below, these motions will likely proliferate.

Moreover, the *Ferrari* petitioners allege that DTP filings outside the vaccine program are on the rise and that some 350 state-law DTP cases were filed in a 4-year period. *See* Geoffrey Evans, *Update on Vaccine Liability in the United States*, 42 CLINICAL INFECTIOUS DISEASES S130, S134 (2006). While these and other vaccine filings hardly illustrate the litigation crisis those petitioners claim warrants preempting all design defect claims,[18] they do suggest that the question presented will recur as these cases work their way through the courts.

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[18]In fact, Dr. Evans, the Director of the Division of Vaccine Injury Compensation at HRSA, does not conclude that there is a current crisis in DTP litigation despite "uncertainty" over autism filings. *Id.* at S136.

B. The Third Circuit's Ruling Robs Families of Important Statutory and Common Law Rights

This Court has repeatedly recognized the importance of resolving questions concerning the scope of express preemption by granting *certiorari* in a variety of such cases in the last two terms. *See, e.g.*, *Altria*, 129 S. Ct. at 543 (2008). Ascertaining the scope of Section 22(b)(1)'s preemption of vaccine design defect claims is no less important than was determining the reach of other express preemption provisions in *Altria* or *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), because it would define the rights the Act affords families to pursue state-law design defect claims against vaccine manufacturers.

As demonstrated, in the Act, Congress expressly preserved the right to pursue state tort claims and expressly preempted state laws that would prohibit individuals from bringing such actions if the claim is not prohibited by the Act itself. All parties here concede that Section 22(b)(1) preempts certain design defect claims if the side effects of the vaccine were unavoidable. The Third Circuit, however, also bars claims involving vaccines for which there were safer alternatives and prevents trial courts from making that determination. As a result, its ruling prevents the hundreds of families alleging injuries from DTP vaccine, and potentially thousands of others alleging injuries from other vaccines, from pursuing tort claims for vaccine-related injuries even though safer alternatives were available at the time.

C. The Third Circuit's Ruling Destroys Incentives for Manufacturers to Develop and Market Better Vaccines

In passing the Act, Congress understood that preserving a stable vaccine supply entails far more than completely immunizing the childhood vaccine industry from most lawsuits. Instead, the relevant committees took pains to strike a balance between providing limited immunity, caring for injured children, and maintaining incentives to make vaccines safer. To that end, "[t]he Act modifies, but does not eliminate, the traditional tort system, which . . . provide important incentives for the safe manufacture and distribution of vaccines." *Schafer*, 20 F.3d at 3. In fact, in its opinion, the Third Circuit admitted that Petitioners' interpretation of Section 22(b)(1) would impose just such an "affirmative obligation" on manufacturers to develop safer vaccines. A-36; *see also Levine*, 129 S. Ct. at 1203 ("state tort suits . . . provide incentives for drug manufacturers to disclose safety risks promptly").

By removing the influence of the tort system, the Third Circuit upsets the balance Congress carefully crafted and destroys incentives to make vaccines better. Worse, it rewards manufacturers who, like Respondents, buy rights to competitors' safer vaccines but put these drugs on the shelf while they market more dangerous ones. The House Energy and Commerce Committee, which had jurisdiction over both phases of the Act's enactment, had warned against just such tinkering.

> Taken together, such a system of Federal no-fault compensation and other rights of

> actions are intended to provide a stable vaccine market with care for the injured and incentives for safety. Weakening either safeguard might dislocate immunization programs by limiting the availability of vaccines or by failing to encourage research and development of better vaccines.

H.R. REP. 100-391(I), at 691. The Third Circuit should have heeded Congress' warning.

III. THE THIRD CIRCUIT'S INTERPRETATION OF SECTION 22(B)(1) IS FATALLY FLAWED

A. The Third Circuit Rewrites Section 22(b)(1)'s Plain Language and Ignores Important Rules of Statutory Construction

The Third Circuit interprets Section 22(b)(1) to omit its conditional phrase "if the injury or death resulted from side effects that were unavoidable . . ." All parties agree that the phrase is conditional and requires case-by-case determination of whether the conditions for preemption have been met. They differ only on the criteria to be used. In fact, even the Third Circuit agrees that the phrase is conditional. A-28. Nevertheless, it finds all design vaccine defect claims unconditionally preempted. In doing so, the Court ignores bedrock statutory construction principles and the statute's plain text.

Where, as here, a court concludes that a statute is susceptible of more than one plausible interpretation and the choice is between recognizing or ignoring its

plain language, that court should accept the statute as meaning what it says. *See, e.g., United States v. John Doe, Inc. I*, 481 U.S. 102, 109 (1987). Moreover, this Court has long recognized the "canon of statutory construction that terms in a statute should not be construed so as to render any provision of that statute meaningless or superfluous." *Beck v. Prupis*, 529 U.S. 494, 506 (2000). In holding all design defect claims expressly preempted despite Section 22(b)(1)'s conditional phrase, the Third Circuit shredded that canon and rendered the phrase a nullity.

B. The Third Circuit Incorrectly Finds that Section 22(b)(1) Provides an Exclusive Remedy, Not a Preemption Defense

The Court justified its wholesale amendment of Section 22(b)(1) by holding that Section 22 as a whole essentially creates an exclusive remedy for vaccine-related injuries resulting from design defects. In so doing, the Court ignored considerable case law, cited above, that holds that the Act does not create exclusive remedies for vaccine-related injuries. *See supra* note 9.

The Court reached its conclusion first by postulating that "[i]f, as plaintiffs claim, Congress intended to carve out from subsection 22(b) a mechanism to enable states to determine what side effects could have been avoided through an alternate design, Congress could have done so in the manner used in subpart (b)(2) [which contains a rebuttable presumption]." A-29. Because Congress did not do so, the Court found that it intended to preempt all design defect claims.

In so holding, the Court effectively reverses the burden of proving "clear and manifest" intent to preempt and the presumption against preemption. *Levine*, 129 U.S. at 1195. Had Congress intended to preclude all design defect claims for vaccines in Section 22(b), it knew how to do so.[19] Yet it did not. Under *Levine*, such silence "is powerful evidence" that Congress did ***not*** intend to preempt all design defect claims. *Levine*, 129 U.S. at 1200.

Worse, the court misapprehends the nature of preemption. The court observes that, "[i]f we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court." A-29. Because case-by-case determination would thus "not bar any design defect claims," *id.*, the Court found all such vaccine claims expressly preempted.

This Court has long held that federal preemption is an affirmative defense on which a defendant has the burden of proof. *See, e.g., Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987). To say, as the court here does, that, because a defendant has the burden to prove that the conditions underlying its preemption defense are satisfied in each case, no claim is preempted, is legally incorrect.

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[19] *See Bates*, 544 U.S. at 449; 42 U.S.C. § 300aa-22(c); 42 U.S.C. § 300aa-11(a)(2)(B); *see also Hasler v. United States*, 718 F.2d 202, 204 (6th Cir. 1983) (discussing an old federal statute expressly creating an exclusive federal remedy for injuries resulting from administration of the swine flu vaccine).

C. The Third Circuit Dismisses *Levine*, *Altria*, *Bates*, and *Cipollone* to Marginalize the Presumption Against Preemption

In *Levine*, this Court reaffirmed that a presumption against preemption applies "in all preemption cases" and can be overcome only by a showing of "clear and manifest" purpose to preempt. 129 S. Ct. at 1194-95. The presumption applies to express preemption clauses, *see, e.g.*, *Lohr*, 518 U.S. at 485, and requires that they be read "fairly but narrowly." *Altria*, 129 S. Ct. at 549; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523 (1992). Thus, when a preemption clause is open to two plausible readings, courts have a "[d]uty to accept the reading that disfavors pre-emption." *Bates*, 544 U.S. at 449.

The presumption is particularly strong here because Congress preempted in a field of traditional state regulation: health and safety. *Altria*, 129 S. Ct. at 543; *Lohr*, 518 U.S. at 485. In addition, because Section 22(e) expressly preempts state law that bars claims the Act does not, "'[t]he case for federal pre-emption is particularly weak [because] Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" *Levine*, 129 S. Ct. at 1200 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989)).

A fair but narrow reading of Section 22(b)(1) mandates case-by-case determination of whether a vaccine is unavoidably unsafe. Because the Third

Circuit found that there were at least two plausible readings of § 22(b)(1), it had a duty to apply the presumption and accept the reading of Section 22(b)(1) that avoids preemption. It failed to do so.

The Court ostensibly used "obstacle" preemption to overcome the presumption against preemption here. A-13-14 (using dicta from *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374, n.8 (2000)). Yet the Court placed no apparent floor on how low an obstacle to the achievement of Congressional purpose case-by-case determination could be before the presumption could be overcome. Thus unfettered, the Court was free to engage in the "freewheeling, extratextual, and broad evaluations of Congressional purpose" Justice Thomas has condemned. *Levine*, 129 S. Ct. at 1217 (Thomas, J., concurring). As a result, the Third Circuit reached a legally unsustainable conclusion about the Act's purpose and text.

D. The Third Circuit Fails to Utilize Crystalline Legislative History Supporting Petitioners' Construction of Section 22(b)(1)

Although the Third Circuit did not consider any legislative history in deciding that Section 22(b)(1) does not permit inquiry into unavoidability, it should have done so because the legislative history supporting such an inquiry is clear and would have assisted the Court in interpreting Section 22(b)(1).

When it amended the Act to fund its compensation program, the House Energy and Commerce Committee made clear that Section 22(b)(1) did not preempt all design defect claims, irrespective of safer alternatives.

It stated:

> With these amendments in place, the Committee believes that a complete system of vaccine compensation can take effect which will provide compensation to those persons who are inadvertently injured by routine immunizations while allowing those persons who believe that they have a claim for remedies in court to pursue it. It is the Committee's intention to create a compensation system that is speedy and generous enough to dissuade petitioners from going on to court. . . [B]oth at the time of the original enactment and in passing this legislation, the Committee acted with the understanding that tort remedies were and are available. . .
>
> * * * *
>
> [T]he codification of Comment (k) of the Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

H.R. REP. 100-391(I), at 691. The Court rejects this legislative history, although in another context, because it contends that it was improper subsequent legislative history and from the wrong committee. A quick review of the relevant committee report reveals its proper pedigree. *Id.* at 690-700. Thus, the only question is whether this crystalline expression of Congressional intent may be discarded as "subsequent" legislative history.

The Third Circuit concedes that "[t]he Vaccine Act . . . made the compensation program and accompanying tort reforms contingent upon the enactment of a tax to provide funding for the compensation." A-36. In fact, in recognition of the fact that the Act was not effective until both parts had been enacted and, at the time, the vaccine tax had not passed, the court, in *Wack*, 666 F. Supp. at 127 n.1, refused to consider the Act as evidence of Congress' intent not to preempt state claims.

In *District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008), this Court distinguished pre-enactment from subsequent legislative history in terms of its effect on a congressional vote. To the extent Congress' vote to fund the vaccine compensation program and make effective its limited liability limits was "contingent" upon assurances that unavoidability would be determined on a case-by-case basis, legislative history from the 1987 amendments cannot be considered "subsequent" and rejected as such.

E. Congress Created and This Court Has Ratified the Dichotomies the Third Circuit Claims Congress Could Never Have Intended

The Third Circuit also rejects the *Ferrari* court's reading of Section 22(b)(1) because it

> [c]ould create an awkward dichotomy in the case law of these states – their courts would be required to engage in case-by-case analysis of all strict liability and negligent design defect claim brought under the Vaccine Act, while barring strict liability design defect claims against prescription drug manufacturers.

A-30. In passing the Act, however, Congress expressly created the very dichotomy the Third Circuit claims it could not have intended when, in Section 22(e), it expressly preempted state law that would prevent the pursuit of state claims not barred by the Act. State litigants are, therefore, expressly authorized to pursue claims against vaccine defendants they might not be able to pursue against other drug manufacturers.

The Third Circuit also ignores the dichotomies this Court ratified in *Riegel, Lohr*, and *Levine*. In *Riegel* and *Lohr*, the Court found state failure-to-warn claims against medical device manufacturers preempted if their devices went through the pre-market approval process, *Riegel*, 128 U.S. at 1006-07, but not if the same manufacturers' products went through the lesser "510(k)" approval process. *Lohr*, 518 U.S. at 513. By contrast, in *Levine*, it found no intent to preempt all

failure-to-warn claims in the alleged comprehensiveness of the New Drug Application process. 129 S. Ct. at 1196. Against this backdrop, it is not surprising – or dispositive – that Congress would have chosen to impose a slightly different burden of proof on vaccine manufacturers who had already been given the considerable advantage of forcing potential litigants to exhaust administrative remedies before they could pursue state-law tort claims.

CONCLUSION

For the reasons stated, this Court should grant the petition for writ of *certiorari*.

Respectfully submitted,

Collyn A. Peddie
Counsel of Record
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway, Suite 600
Houston, Texas 77017
Telephone: (713) 230-2200
Facsimile: (713) 643-6226

Attorneys for Petitioners, Russell, Robalee, and Hannah Bruesewitz

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 07-3794

RUSSELL BRUESEWITZ; ROBALEE BRUESEWITZ,
parents and natural guardians of Hannah Bruesewitz, a minor child and in their own right,

Appellants

v.

WYETH INC.
f/k/a
WYETH LABORATORIES,
WYETH-AYERST LABORATORIES,
WYETH LEDERLE,
WYETH LEDERLE VACCINES,
AND LEDERLE LABORATORIES

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
District Court No. 05-cv-05994
District Judge: The Honorable Michael M. Baylson

Argued September 11, 2008
Before: McKEE, SMITH, and WEIS, *Circuit Judges*
(Filed: March 27, 2009)

Collyn A. Peddie (Argued)
Williams, Kherkher, Hart & Boundas
8441 Gulf Freeway
Suite 600
Houston, TX 77017-5001
Counsel for Appellant

Reetu Dandora
1650 Market Street
2500 One Liberty Place
Philadelphia, PA 19103-7301
Counsel for Appellee

Lauren Elliott
Richard W. Mark (Argued)
Daniel J. Thomasch
Orrick, Herrington & Sutcliffe
666 Fifth Avenue
New York, NY 10103
Counsel for Appellee

Henry F. Reichner
Michael T. Scott
Reed Smith
1650 Market Street
2500 One Liberty Place
Philadelphia, PA 19103
Counsel for Appellee

OPINION

SMITH, *Circuit Judge*.

This appeal presents three questions related to the National Childhood Vaccine Injury Act: (1) whether the Act preempts all design defect claims against the manufacturer of a vaccine; (2) whether the plaintiffs demonstrated that the manufacturer failed to adequately warn the plaintiffs of the risks associated with the vaccine; and (3) whether the plaintiffs provided sufficient evidence of a manufacturing defect to survive the defendant's motion for summary judgment. The District Court held that the Act preempted all design defect claims and concluded that the plaintiffs failed to provide sufficient evidence to support the other two claims. For the reasons that follow, we will affirm.

I.

A.

Historically, the states have possessed "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet" of their citizens. *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985). This has been true with regard to drugs, as the Supreme Court has declared it "well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen v. Roe*, 429 U.S. 589, 603 (1977). And the police powers extend to

immunization, as state and local authorities have responded to illnesses like smallpox and sought to inoculate members of the populous. Center for Biologics Evaluation and Research, Food and Drug Administration, *Science and the Regulation of Biological Products: From a Rich History to a Challenging Future* 8 (2002). Despite calls in the late nineteenth-century for the federal regulation of vaccines to promote uniform safety regulations, Congress did not act until 1902, when thirteen children died after being vaccinated with contaminated diptheria antitoxin. *Id.* at 12. Over the past century, however, the federal government has taken a predominate role in approving, regulating, and promoting vaccines—from the passage of the Biologics Control Act in 1902, Pub. L. No. 57-244, which authorized a federal agency to issue regulations related to vaccines, to the Public Health Service Act, Pub. L. No. 78-410, which required federal authorities to license vaccines and vaccine manufacturers, to the Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States, Pub. L. No. 107-9, which appropriated money for the acquisition of a sufficient quantity of the smallpox vaccine to inoculate the country.

The National Childhood Vaccine Injury Act ("Vaccine Act") is one such effort. P.L. 99-660, Title III, 100 Stat. 3743, 3756–3784 (codified at 42 U.S.C. § 300aa-1 *et seq.*). Enacted in 1986, the Vaccine Act established a national vaccine program to "achieve optimal prevention of human infectious diseases

through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. It sought to accomplish this primarily through the creation of the National Vaccine Injury Compensation Program ("NVICP") for claims against drug manufacturers for vaccine-related injuries and deaths. 42 U.S.C. § 300aa-10 *et seq.*

The NVICP has two parts. Part A creates a mandatory forum for the administration of claims—it requires a petitioner seeking compensation, including the injured party's legal representative, to file a petition in the "Vaccine Court," which is part of the United States Court of Federal Claims. *Id.* at § 300aa-11. The petitioner is entitled to receive compensation if: (1) the affected person received a vaccine covered by the Vaccine Act; (2) the affected person suffered a "Table injury";[1] and (3) it cannot be shown by a preponderance of the evidence that the injuries or death were not caused by the vaccine. *Id.* at §§ 300aa-11, 300aa-13. Alternatively, a petitioner who suffers a non-Table injury may still obtain compensation by proving affirmatively that the vaccine caused the injury. *See Grant v. Sec'y of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Part B of the NVICP permits a petitioner, after the Vaccine Court has issued a final judgment, to either accept or reject that judgment. 42

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[1]The Vaccine Act created the "Vaccine Injury Table." 42 U.S.C. § 300aa-14. It sets forth the "vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration" of vaccines for which individuals may seek compensation. *Id.*

U.S.C. § 300aa-21 *et seq.* If the petitioner rejects the judgment, she may pursue certain limited claims in state or federal court.[2] 42 U.S.C. § 300aa-21.

B.

Hannah Bruesewitz was born on October 20, 1991. At the time, the federal Advisory Committee on Immunization Practices recommended that children receive five doses of the diphtheria-pertussis-tetanus ("DPT") vaccine during the course of their childhood, one dose at each of the following ages: (1) 2 months; (2) 4 months; (3) 6 months; (4) 15-18 months; and (5) 4-6 years. Hannah received her first three shots of the DPT vaccine according to this schedule. After the third DPT shot, marketed under the trade name TRI-IMMUNOL and administered on April 1, 1992, she suffered a series of seizures. Doctors subsequently diagnosed Hannah as having residual seizure disorder and developmental delay. Hannah, who is now seventeen, will likely require some medical care related to that condition for the remainder of her life.

Defendant Wyeth, Inc. and its predecessors[3]

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[2]The party also has the option of appealing the Court of Federal Claims' judgment to the United States Court of Appeals for the Federal Circuit. 42 U.S.C. § 300aa-12(f).

[3]The National Health Institute first issued a product license for TRI-IMMUNOL in 1948 to American Cyanamid Company ("Cyanamid"). Lederle Laboratories, an unincorporated division of Cyanamid, produced TRIIMMUNOL. In 1994, American Home Products Corporation ("AHPC") acquired

("Wyeth") manufactured TRI-IMMUNOL until 1998. Approved in 1948, this vaccine contains the "whole-cell" pertussis vaccine—it is prepared using whole, inactivated pertussis bacterial cells. Although the whole-cell vaccine effectively reduced pertussis infections and deaths associated with these infections, it was also linked to a variety of adverse events. This led to interest in and efforts to develop a safer, acellular pertussis vaccine.

In December 1991, the Food and Drug Administration ("FDA") approved the defendant's application for an alternate DPT vaccine, which was known as ACEL-IMUNE. ACEL-IMUNE contains an acellular pertussis component. While the acellular vaccine contains parts of pertussis bacterial cells, because it does not contain a complete cell, it has less endotoxin and is less likely to cause adverse events.[4] The FDA initially approved ACEL-IMUNE, however, for administration as the fourth and/or fifth DPT dose in the series of five. The FDA did not approve an

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Cyanamid. In March 2002, AHPC changed its name to Wyeth.

[4]The acellular pertussis vaccine contains pertussis toxin and other bacterial components. These components, however, are less reactive and cause fewer adverse events because they have been detoxified using chemical or genetic techniques. Centers for Disease Control and Prevention, Pertussis Vaccination: Acellular Pertussis Vaccine for the Fourth and Fifth Doses of the DPT Series; Update to Supplementary ACIP Stat Recommendations of the Advisory Committee on Immunization Practices, October 9, 1992, http://www.cdc.gov/mmwr/preview/mmwrhtml/00048610.htm.

acellular pertussis vaccine for the first three shots in the series until July 1996 when it approved the license of Connaught Laboratories, Inc. Defendant's ACEL-IMUNE did not receive approval for these same doses until December 1996.

Nonetheless, at the time of vaccination in April 1992, Hannah's doctor administered the TRI-IMMUNOL vaccine because there were no acellular pertussis vaccines commercially available for the third dose. Hannah's particular vaccine came from a lot that generated sixty-five reports of adverse reactions with the FDA and Centers for Disease Control and Prevention, including thirty-nine emergency room visits, six hospitalizations, and two deaths. Hannah's physician later indicated, as part of this litigation, that she would not have immunized Hannah had she known of the adverse event reports associated with this lot of the vaccine.

In 1998, Wyeth voluntarily discontinued manufacturing TRI-IMMUNOL.

C.

Hannah's parents ("plaintiffs") filed a petition in the Vaccine Court in April 1995, alleging that Hannah suffered an on-Table residual seizure disorder and encephalopathy.[5] *Bruesewitz v. Sec'y of Dep't of HHS*,

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[5]Effective March 10, 1995, approximately one month before the plaintiffs filed their petition with the Vaccine Court, new regulations deleted residual seizure disorder as a Table

No. 95-0266V, 2002 WL 31965744, at *1 n.1 (Fed. Cl. Dec. 20, 2002). The Court held a hearing in July 2002 and concluded in December of that year that Hannah's injuries were non-Table injuries and that the petitioners had not proven causation in fact. *Id.* at *13–17. Accordingly, it dismissed the claim with prejudice. *Id.* at *17. Hannah's parents rejected the Court's judgment on February 14, 2003.

Having exhausted their administrative remedies, the plaintiffs filed a Complaint in the Philadelphia Court of Common Pleas in October 2005. The complaint sought recovery on four claims: (I) negligent failure to produce a safer vaccine; (II) negligent failure to warn; (III) strict liability for design defect; and (IV) strict liability for manufacturing defect. Wyeth removed the action on the basis of diversity to the Eastern District of Pennsylvania and filed a motion for summary judgment. The District Court denied the motion without prejudice because the parties had not engaged in discovery. Following completion of discovery, Wyeth again moved for summary judgment on all four counts.

Although the District Court did not accept all of Wyeth's theories, it granted summary judgment in Wyeth's favor on all counts on August 24, 2007. The

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injury for DPT vaccine. *Bruesewitz v. Sec'y of Dep't of HHS*, No. 95-0266V, 2002 WL 31965744, at *1 n.1 (Fed. Cl. Dec. 20, 2002); *see also* National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7689–91 (Feb. 8, 1995).

District Court concluded that Section 22(b)(1) of the Vaccine Act, 42 U.S.C. § 300aa-22(b)(1), preempts all design defect claims arising from a vaccine-related injury or death and dismissed Counts I and III on that basis. Regarding Count II, which alleged negligent failure to warn, the District Court concluded that the plaintiffs had not rebutted the statutory presumption created by Section 22(b)(2) of the Vaccine Act, 42 U.S.C. § 300aa-22(b)(2), that Wyeth's FDA-compliant warnings were proper. As to Count IV, which alleged that the particular lot from which Hannah's dose originated was especially prone to adverse reactions due to a manufacturing defect, the District Court concluded that the plaintiffs had failed to present sufficient evidence that the lot was defective or that it caused Hannah's injuries.

The District Court's ruling on the first and third claims warrants further examination. Both counts alleged a design defect—Count I alleged that Hannah's vaccine was negligently designed because the defendant knew of a safer alternative and failed to produce it, while Count III alleged strict liability design defect. The District Court ruled that both claims were preempted by the Vaccine Act. It rested this decision on four points. First, it stated that a case-by-case consideration of whether a vaccine was unavoidably safe would not protect vaccine manufacturers from suit. Second, it reasoned that Congress passed the Vaccine Act to "provide an umbrella under which manufacturers would improve the safety of their products while remaining immune from design defect claims." Third, the Court found that

Congress achieved an appropriate balance by offsetting the effect of the preemption of design defect claims with creation of a compensation program for individuals injured by vaccines. Finally, it concluded that the Vaccine Act preempts both strict liability and negligent design defect claims against FDA-approved vaccines. Accordingly, it dismissed plaintiffs' first and third claims.

The plaintiffs appealed. Their appeal presents this Court with three questions: (1) does § 300aa-22(b)(1) act as a complete bar to design defect claims; (2) have the plaintiffs in this case met their burden under § 22(b)(2) of the Vaccine Act to show that defendants failed to provide an adequate warning of the alleged dangers of the vaccine; and (3) have the plaintiffs provided sufficient evidence of a manufacturing defect to survive the defendant's motion for summary judgment.

II.

The District Court had jurisdiction under 28 U.S.C. §§ 1332 and 1441, and we have appellate jurisdiction under 28 U.S.C. § 1291. Our review of a District Court's grant of summary judgment is plenary, and we apply the same standard as the District Court to determine whether summary judgment was appropriate. *Norfolk S. Ry. Co. v. Basell USA Inc.*, 512 F.3d 86, 91 (3d Cir. 2008). A grant of summary judgment is appropriate "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any

material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In making this determination, we must view the facts in the light most favorable to the nonmoving party and draw all inferences in that party's favor. *Norfolk*, 512 F.3d at 91.

III.

Preemption doctrine is rooted in the Supremacy Clause of the United States Constitution. Article VI declares that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Under the Supremacy Clause, federal law may supersede state law in several different ways." *Hillsborough County, Fla., v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985). Over the years, the Supreme Court has recognized three types of preemption: express preemption, implied conflict preemption, and field preemption. *Id.*

A federal enactment expressly preempts state law if it contains language so requiring. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001). Thus, when construing an express preemption clause, a reviewing court must necessarily begin by examining the "plain wording of the clause," as this "necessarily contains the best evidence of Congress' pre-emptive intent." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62–63 (2002) (quoting *CSX Transp. v. Easterwood*, 507 U.S. 658, 664 (1993)). Though the language of the

provision offers a starting point, courts are often called upon to "identify the domain expressly pre-empted by that language." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996) (internal quotation marks and citations omitted). This, in turn, is guided by two principles. *Id.* at 485. First, "Congressional purpose is the 'ultimate touchstone' of our inquiry." *Lorillard Tobacco Co.*, 533 U.S. at 541 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)); *see also Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008) ("If a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains."). Second, courts must operate under the "assumption that the historic police powers of the States [a]re not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress." *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997).

Implied conflict preemption arises when state law conflicts with a federal statute in one of two situations. First, it arises when it is "impossible for a private party to comply with both state and federal requirements." *English v. General Elec. Co.*, 496 U.S. 72, 78–79 (1990). It is also present when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Furthermore, implied preemption may exist even in the face of an express preemption clause. As the Supreme Court observed in *Freightliner Corp. v.*

Myrick, 514 U.S. 280, 288 (1995), "Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not pre-empted," but that "does not mean that the express clause entirely forecloses any possibility of implied pre-emption."

When confronting arguments that a law stands as an obstacle to Congressional objectives, a court must use its judgment: "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). In fact, we must look to "'the entire scheme of the statute'" and determine "'[i]f the purpose of the [federal] act cannot otherwise be accomplished—if its operation with its chosen field [would] be frustrated and its provisions be refused their natural effect.'" *Id.* (quoting *Savage v. Jones*, 225 U.S. 501, 533 (1912)). Once again, this requires an examination of the "'whole law, and to its object and policy.'" *Gade v. Nat'l Solid Wastes Mgmt. Assn.*, 505 U.S. 88, 98 (1992) (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987)).

Field preemption arises by implication when state law occupies a "field reserved for federal regulation." *United States v. Locke*, 529 U.S. 89, 111 (2000). This occurs when "Congress [] left no room for state regulation of these matters." *Id.*; *see also Lorillard Tobacco Co.*, 533 U.S. at 541. It may also be inferred when "an Act of Congress 'touch[es] a field in which the federal interest is so dominant that the

federal system will be assumed to preclude enforcement of state laws on the same subject.'" *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Nonetheless, because field preemption typically arises in areas traditionally regulated by states under their police powers, "congressional intent to supersede state laws must be 'clear and manifest.'" *Id.* (citation omitted).

Yet despite the development of the foregoing preemption jurisprudence, courts must begin their analysis of these questions by applying a presumption against preemption. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). "In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" *Bates v. Dow AgroSciences*, 544 U.S. 431, 449 (2005). When faced with two equally plausible readings of statutory text, we "have a duty to accept the reading that disfavors preemption." *Id; see also Altria Group, Inc.*, 129 S. Ct. at 543; *Cipollone*, 505 U.S. at 518. This is true even in the event of an express preemption clause. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1014 (2008) (quoting *Bates*, 544 U.S. at 449). That issues of health and safety have traditionally fallen within the province of state regulation is beyond refute. That safety of vaccines is an issue of health and safety is equally clear. *See, e.g., Medtronic, Inc.*, 518 U.S. at 485. Nonetheless, in the face of clear evidence, the presumption against preemption can be overcome. *See Crosby*, 530 U.S. at 374 n.8. ("Assuming, *arguendo*,

that some presumption against preemption is appropriate, we conclude, based on our analysis below, that the state Act presents a sufficient obstacle to the full accomplishment of Congress's objectives under the federal Act to find it preempted.").

We must decide here whether the plaintiffs' design defect claims are preempted. As we have noted, the District Court reasoned that four points counseled in favor of finding that both claims were preempted by the Vaccine Act: (1) if the Vaccine Act permitted case-by-case consideration of design defect claims, the Act would do little to protect manufacturers from suit; (2) Congress intended the Vaccine Act to encourage vaccine improvements while providing immunity for design defect claims; (3) Congress achieved a balance between manufacturers and patients by creating the compensation system to offset design defect immunity; and (4) the Vaccine Act is broader than comment k of the Restatement (Second) of Torts § 402A such that the Act encompasses both strict liability and negligence claims. At the same time, the District Court did not explicitly lay out a framework for coming to these conclusions, nor did it state whether they were predicated on express, implied, or field preemption grounds.

Plaintiffs now seek to turn such ambiguity to their advantage by arguing that the District Court's decision was "based on some kind of implied or field preemption" when the defendant's motion for summary judgment raised only express preemption. This, they maintain, violated "well-settled summary

judgment principles."[6] Accordingly, we must consider four questions related to the preemption of the design defect claim: (1) whether § 300aa-22(b) constitutes an express preemption provision; (2) whether we may use traditional tools of statutory interpretation, including legislative history, when construing such a provision; (3) whether this provision preempts plaintiffs' design defect claims; and (4) whether the District Court's decision is consistent with this analysis.

A.

Part B of the Vaccine Act establishes the circumstances under which individuals who have rejected the judgment of the Vaccine Court may subsequently file suit in state or federal court. Section 300aa-22, entitled "Standards of Responsibility," sets

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[6]The plaintiffs argue that the District Court's decision violates the principle that a "district court may not grant summary judgment *sua sponte* on grounds not requested by the moving party." *John Deere Co. v. Am. Nat'l Bank*, 809 F.2d 1190, 1192 (5th Cir. 1987). This Court has previously remanded a claim because the District Court granted summary judgment on a ground not offered in the moving party's motion. *Brobst v. Columbus Servs. Intern.*, 761 F.2d 148, 159 (3d Cir. 1985). For the reasons that follow, we need not decide this issue. We note, however, that our ruling in *Brobst* was predicated on a district court's obligation to provide notice to the parties before ruling on a particular issue. In this case, the plaintiffs argued in their response to the motion for summary judgment about the propriety of ruling on implied preemption grounds, thereby indicating that they were on notice that the District Court may have been considering implied preemption at that time and furthermore that they had an opportunity to respond on this issue.

forth both a general rule and several exceptions to that rule. It states:

> (a) General rule
> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (b) Unavoidable adverse side effects; warnings
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
>
> (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 *et seq.*] and section 262 of this title (including regulations issued under such provisions) applicable

to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings
No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction
The standards of responsibility prescribed by this section are not to be

> construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.
>
> (e) Preemption
> No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

42 U.S.C. § 300aa-22.

We are guided by two cases interpreting language similar to that which appears in § 300aa-22. In *Lorillard Tobacco Co.*, the Supreme Court interpreted the Federal Cigarette Labeling and Advertising Act, which stated that "'[n]o statement relating to smoking and health other than the statement required by section 1333 of this title, shall be required on any cigarette package.'" 533 U.S. at 541 (quoting 15 U.S.C. § 1334). This language is analogous to subsection 22(b)(1) of the Vaccine Act, which states that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable." In both provisions,

without using language such as "no state shall" or "state law is preempted," Congress has set forth an area in which state law may not operate. In *CSX Transportation, Inc.*, the Supreme Court construed the following provision: "A state may adopt or continue in force any law . . . until such time as the Secretary has adopted a rule . . . covering the subject matter of such State requirement. A state may adopt or continue in force an additional or more stringent law . . . when not incompatible with any Federal law. . . ." 507 U.S. at 662 & n.2 (quoting 45 U.S.C. § 434 (repealed 1994)). Similarly, Section 22(a) of the Vaccine Act establishes a general rule permitting states to regulate vaccines subject to several exceptions set forth in subsections (b), (c), and (e).

In both *Lorillard Tobacco Co.* and *CSX Transportation, Inc.*, the Supreme Court characterized the language at issue as an express preemption provision. In the former case, the Court declared that "Congress unequivocally preclude[d] the requirement of any additional statements on cigarette packages beyond those provided in § 1333." *Lorillard Tobacco Co.*, 533 U.S. at 542. In the latter case, the Court characterized the quoted language as containing "express saving and preemption clauses." *CSX Transp., Inc.*, 505 U.S. at 662. Accordingly, we conclude that § 22(a) and § 22(b)(1) of the Vaccine Act also contain express preemption clauses.

Our conclusion is consistent with prior jurisprudence from this Court, stating that express preemption "arises when there is an explicit statutory

command that state law be displaced." *St. Thomas-St. John Hotel & Tourism Ass'n, Inc. v. Gov't of the U.S., V.I.*, 218 F.3d 232, 238 (3d Cir. 2000). Section 22(a) clearly states Congress's intent to displace state law in several enumerated instances, including as provided for in subsection (b). Subsection (b) then declares that manufacturers are immune from liability for claims arising from "unavoidable" injuries and deaths related to vaccine administration, thereby prohibiting states from regulating in this area. The scope of a preemption provision stating that "no state shall pass laws with the following exceptions" may well be broader than a provision stating "state law applies with the following exceptions." Yet the breadth of a provision does not alter the import of the underlying language, and here that language conveys a clear intent to override state law civil action claims in particular, defined circumstances.

Yet we must still determine the scope and reach of the express preemption provision. The plaintiffs here concede that the statute "expressly precludes only those state tort claims involving vaccines with side effects first shown to be 'unavoidable,'" but they argue that avoidability must first be determined "on a case-by-basis" as part of a court's examination of a design defect claim. In response, Wyeth argues that this language "preempts all claims arising from allegations of design defect." Accordingly, "we must [] 'identify the domain expressly pre-empted' by [the] language" of the Vaccine Act. *Medtronic Inc.*, 518 U.S. at 484.

B.

Again, we are mindful that courts seeking to identify the scope of an express preemption provision are compelled to consider "Congressional purpose [] the 'ultimate touchstone' of our inquiry." *Lorillard Tobacco Co.*, 533 U.S. at 541 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)). The Supreme Court has declared on numerous occasions that reviewing courts have several tools to aid them in their interpretation of congressional purpose. Courts may be guided by the "structure and purpose of the statute as a whole, as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Medtronic, Inc.*, 518 U.S. at 486 (internal quotation marks and citations omitted); *see also Gade*, 505 U.S. at 98 ("Our ultimate task in any pre-emption case is to determine whether state regulation is consistent with the structure and purpose of the statute as a whole."); *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990) ("To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute."). Beyond structure and purpose, the Court has also stated "that '[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'" *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987) (quoting *Kelly v. Robinson*, 479 U.S. 36, 43 (1986).

The above analysis, allowing courts to consider

a statute's purpose, structure, and regulatory scheme, applies even in light of the presumption against preemption. The Court's preemption discussion in *Cipollone* is particularly instructive on this point. In that case, the Court considered a statute stating that "[n]o statement relating to smoking and health shall be required in the advertising of [properly labeled] cigarettes." *Cipollone*, 505 U.S. at 518 (internal quotations and emphasis omitted). The Court reaffirmed the presumption against preemption. *Id.* at 516. It also noted the existence of an express preemption clause, *id.* at 517, which it construed using several tools of statutory construction, *id.* at 519. The Court noted the Act's explicit "statement of purpose," and it read this against a "backdrop of regulatory activity." *Id.* It also considered the "regulatory context," namely the factors that served as "the catalyst for the passage" of the statute. *Id.* The Court stated that this backdrop and context supported a narrow reading of the preemption clause. *Id.* at 518–19. In dissent, Justice Scalia criticized the majority and argued for a broader interpretation of the provision, predicated on the statute's use of the phrase "no statement." *Id.* at 549–50 (Scalia, J., dissenting). The majority rejected Justice Scalia's interpretation because it "relie[d] solely on an interpretation of those two words, artificially severed from both textual and legislative context." *Id.* at 519 n.16.

We have recognized that legislative history is not without its shortcomings as a tool of interpretation. "As a point of fact, there can be multiple legislative intents because hundreds of men

and women must vote in favor of a bill in order for it to become a law." *Morgan v. Gay*, 466 F.3d 276, 278 (3d Cir. 2006); *see also Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005) (noting that "legislative history is itself often murky, ambiguous, and contradictory," and that it "may give unrepresentative committee members—or, worse yet, unelected staffers and lobbyists—both the power and the incentive to . . . secure results they were unable to achieve through the statutory text"). Yet, resort to legislative history is appropriate "when necessary to interpret ambiguous statutory text." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 187 n.8 (2004) (plurality opinion). Although this Court has declined to employ legislative history if a statute is clear on its face, we have allowed recourse to legislative history in the face of ambiguity. *See, e.g., In re Mehta*, 310 F.3d 308, 311 (3d Cir. 2002) ("We look to the text of a statute to determine congressional intent, and look to legislative history only if the text is ambiguous."); *United States v. Gregg*, 226 F.3d 253, 257 (3d Cir. 2000) ("To determine a law's plain meaning, we begin with the language of the statute. If the language of the statute expresses Congress's intent with sufficient precision, the inquiry ends there . . . Where the statutory language does not express Congress's intent unequivocally, a court traditionally refers to the legislative history . . . .").

It is, therefore, appropriate to consider legislative history to resolve ambiguity in the scope of an express preemption provision. In *Cipollone*, as part of the discussion of the regulatory context of the

statute at issue, the Court cited language from a House of Representatives' report that was issued during Congress's consideration of the legislation. *Cipollone*, 505 U.S. at 519. Similarly, in *Lorillard Tobacco Co.*, the Court stated that its task was to "identify the domain expressly pre-empted," 533 U.S. at 541, and that this was aided "by considering the predecessor pre-emption provision and the circumstances in which the current language was adopted." *Id.* at 542. It went on to cite reports from the United States Surgeon General, the House of Representatives, and the Senate in the course of its discussion. *Id.* at 542–44.

We cannot resolve from statutory text alone the scope of the express preemption provision before us. Accordingly, we will look at the language, structure, and purpose of the Vaccine Act to ascertain whether it preempts all design defect claims, and we will resort—as we must—to legislative history to aid our interpretation.

C.

We are left to construe the scope of preemption created by the phrase "if the injury or death resulted from side effects that were unavoidable . . . ." § 300aa-22(b). The phrase hinges on the word "unavoidable," yet the term is not defined in the Vaccine Act. Nor does the surrounding language answer questions such as whether all design defect claims are preempted or whether state courts may determine avoidability on a case-by-case basis. According to the *Oxford English*

Dictionary, "unavoidable" means "[n]ot avoidable; that [which] cannot be avoided or escaped; inevitable." (2d ed. 1989). By itself, this succinct definition is unhelpful. Yet, the structure of the provision as a whole provides necessary context, and we can conceive of two possible interpretations of this language.

1.

The first construction would result in the preemption of some design defect claims. Subsection (a) expressly preempts state law to the degree indicated in subsection (b). Subsection (b), in turn, primarily relates to design defect claims, as evidenced by the use of a subordinate clause introduced by "even though" to reference claims that might arise from a manufacturing defect or warning defect. That structure makes it clear that we must consider design defects in the first instance. Clearly, then, subsection (a) and (b) work in concert to preempt state law and exempt manufacturers from liability for some design defect claims.

Section 300aa–22, taken as a whole, further clarifies Congress's intent with regard to design defect claims. Subsection (a) displaces state law only as defined in subsections (b), (c), and (e). Subsections (b) and (c) employ identical introductory language, stating that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . ." Subsection (e) prohibits states from foreclosing civil actions that are otherwise "not barred

by this part," thereby stating that other parts of § 300aa-22 are designed to not only limit liability but bar some claims entirely. Thus, by reading these three provisions together, it becomes clear that Congress intended that subsections (b) and (c) should be an outright bar to some claims.

In a case presenting design defect claims similar to those in the present case, the Georgia Supreme Court reached a different conclusion regarding the meaning of § 22(b). *Am. Home Prods. Corp v. Ferrari*, 669 S.E.2d 236 (Ga. 2008). It focused on the clause "if the injury or death resulted from side effects that were unavoidable." That Court first noted that this language is conditional and implies that some vaccine-related injuries and deaths may be avoided. *Id.* at 240. The *Ferrari* Court also reasoned that reading the preemption provision to exclude all design defect claims would render the clause superfluous. *Id.* at 240. That Court concluded that if Congress intended to preempt all design defect claims, it could have achieved that result by omitting the "unavoidable" clause such that the provision would prevent liability "if the vaccine was properly prepared and was accompanied by proper directions and warnings." *Id.*

We do not consider the *Ferrari* Court's reading to be compelling. First, while we recognize that the language is conditional, such a reading does not foreclose the preemption of some claims. Furthermore, it is always possible to construct through hindsight an alternate structure for a statute with alternative wording that would render it more clear. For instance,

subpart (b)(1) notes that manufacturers may not be liable for unavoidable side effects caused by a vaccine that was "properly prepared and was accompanied by proper directions and warnings," and subpart (b)(2) sets limits on this. In subpart 22(b)(2), the statute declares that vaccines issued in accordance with federal labeling requirements are presumed to have proper directions and warnings *unless* one of the following applies: (1) the manufacturer engaged in conduct that would subject it to punitive damages under § 300aa-23 of the Vaccine Act, or (2) there is clear and convincing evidence that the manufacturer failed to exercise due care. § 300aa-22(b)(2). If, as plaintiffs claim, Congress intended to carve out from subsection 22(b) a mechanism to enable states to determine what side effects could have been avoided through an alternate design, Congress could have done so in the manner used in subpart (b)(2) to preserve some warning defect claims against vaccines that meet federal labeling requirements.

More importantly, we think the *Ferrari* Court's construction is contrary to the structure of the Act because it does not bar any design defect claims. If we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court. Furthermore, in 1986 when Congress enacted the Vaccine Act, several courts had already barred strict liability design defect claims against prescription drug manufacturers under state

law.[7] The *Ferrari* Court's construction of § 300aa-22 could create an awkward dichotomy in the case law of these states—their courts would be required to engage in case-by-case analysis of all strict liability and negligent design defect claims brought under the Vaccine Act, while barring strict liability design defect claims against prescription drug manufacturers. As discussed above, Congress could not have intended such a result, as § 300aa-22 makes clear that Congress intended to preempt and bar certain claims.

Though there are two possible interpretations of subsection (b), we conclude that a "clear and manifest" expression of congressional intent supports the first interpretation.[8] Our construction, however, does not

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[7]*See, e.g., Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 128(9th Cir. 1968); *Lewis v. Baker*, 413 P.2d 400, 404 (Or. 1966) (overruled in part on other grounds).

[8]In *Wyeth v. Levine*, S. Ct. 8 , No. 06-1249, 2009 WL 529172, at *1 (2009), the Supreme Court examined whether federal law preempted state tort claims alleging that a drug manufacturer failed to adequately warn of the dangers associated with a drug. *Id.* at *1. Though we recognize that the Supreme Court concluded that state tort law claims were not preempted in that case, *id.* at 13, Levine is readily distinguishable on several grounds. First, the Court explicitly noted the absence of an express preemption provision and found Congress's silence, "coupled with its certain awareness of the prevalence of state tort litigation, [] powerful evidence." *Id.* at 10. In this case, however, Congress included an express preemption provision that was prompted, as evidenced by the Committee Report, by the prevalence of state tort litigation. Second, it recognized that, under federal law, a drug manufacturer could strengthen a drug's

indicate whether subsection (b) preempts all design defect claims or only strict liability design defect claims.

2.

There is no language in the statute indicating whether the Vaccine Act preempts only strict liability design defect claims or also those based in negligence, and the structure and purpose of the Act are of little assistance in resolving that question. As a result, there remains some inherent ambiguity in the statute, and we must resort to legislative history to resolve that ambiguity. The parties in this case cite to different congressional reports to support their claims. Each argument will be addressed in turn.

a.

Wyeth cites to a report ("Commerce Report") from the House Committee on Energy and Commerce ("Energy and Commerce Committee"), which had jurisdiction over the Vaccine Act and guided the legislation through passage. H.R. Rep. No. 99-108 (1986). The Commerce Report declared that childhood vaccinations have been "one of the most spectacularly effective public health initiatives this country has ever undertaken," preventing countless deaths and saving billions of dollars. *Id.* at 4. The Report stated, however,

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label without preapproval from the FDA. *Id.* at 7. This stands in contrast to the FDA's far-more extensive control and oversight of the approval of a drug's design and alteration.

that "the Nation's ability to maintain this level of success has come into question" as a result of tort claims by individuals gravely injured by vaccines. *Id.* This, in turn, caused an increase in the cost of vaccines, the withdrawal of some manufacturers from the market, and a decreased rate of immunization. *Id.* The Report noted that these conditions prompted the Energy and Commerce Committee to reevaluate the federal regulation of vaccines. *Id.* at 5.

Though the Committee was concerned with compensating individuals injured by vaccines, it also sought to reduce the cost of such claims in order to safeguard the development and availability of such vaccines. It noted that there was "no 'perfect' or reaction-free childhood vaccine on the market" and that a small number of children suffered serious reactions. *Id.* at 6. It then stated that "despite these possibilities . . . it is safer to take the required shots than to risk the health consequences of contracting the diseases . . . ." *Id.* The Committee expressed concern that the "withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." *Id.* at 7. The Report demonstrates that the Vaccine Act was motivated in great measure by Congress's belief that an alternate compensation system would reduce awards and create a stable, predictable basis for estimating liability: "[T]he Committee believes that once this system is in place and manufacturers have a better sense of their potential litigation obligations, a more stable childhood

vaccine market will evolve." *Id.*

Importantly, the Commerce Report specifically addressed § 300aa-22, the section at issue here. First, it noted that some provisions of the Vaccine Act would "change most State laws" related to vaccine injuries and deaths. Yet, it deemed this an appropriate change "in light of the availability of a comprehensive and fair compensation system." *Id.* at 25. Then, the Commerce Report stated that the Vaccine Act reflected the *principle* of Restatement (Second) of Torts § 402A comment k,[9] which states that sellers of certain

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[9]The Georgia Supreme Court took this reference to mean that Congress intended to preserve some design defect claims and permit case-by-case consideration of whether a vaccine is unavoidably harmful. *See Ferrari,* 668 S.E.2d at 239–40. Specifically, the *Ferrari* Court pointed to the fact that a majority of courts have interpreted comment k as permitting a case-bycase analysis of whether a vaccine's side effects are avoidable. *Id.* at 239. It then drew on the Vaccine Act's legislative history to support its conclusion that Congress interpreted comment k in the same manner as those other courts. *Id.* at 240.

Though we acknowledge that a majority of states permit some design defect claims under comment k, we disagree with the Georgia Supreme Court on the relevance of this fact. First, it discounts that courts in a significant minority of states have held that comment k preempts all strict liability design defect claims against FDA-approved drugs. Second, the current state of affairs with regard to the interpretation of comment k tells us little about what Congress knew in 1986 when it passed the Vaccine Act. As one court has noted, "in 1986 courts had not yet reached a consensus on the meaning of Comment k, or the proper treatment of prescription drugs in design defect legislation. Thus, while some courts concluded that a case-by-case analysis was necessary . . . others concluded that prescription drug manufacturers were

products, including vaccines, should not be strictly liable for harm caused by their products when it is not possible to make these products entirely safe.[10] *Id.* at 25–26. The Report described the type of vaccine cases

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generally not liable for design defect claims." *Militrano v. Lederle Labs.* 769 N.Y.S.2d 839, 844–45 (N.Y. Sup. Ct. 2003). Finally, we note that regardless of state court consideration of comment k, we believe Congress made it clear what it intended when it invoked comment k.

[10]Comment k states the following:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to both serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt k (1966).

in which comment k would have import—cases in which innocent children would be "badly injured or killed" by a vaccine, but in which a jury would likely impose liability on the manufacturer "even if the defendant manufacturer *may* have made as safe a vaccine as anyone reasonably could expect." H.R. Rep. 99–908 at 26 (emphasis added). Finally, it stated in precise and certain terms that its reference to comment k and the language of 22(b) results in immunity for liability for all design defects, whether liability rests on theories of strict liability or negligence: "[i]f [injured individuals] cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system." *Id.*

In our view, the Commerce Report supports the conclusion that the Vaccine Act preempts all design defect claims, including those based in negligence. First, the Committee Report repeatedly stressed the importance of vaccine development and availability. Second, it expressed serious concern over the withdrawal of even a single vaccine manufacturer from the marketplace. Third, though it described a regime that sought to compensate individuals, the Commerce Report emphasized that the new system would reduce and stabilize litigation costs while also enabling manufacturers to estimate the costs associated with compensation. Finally, it explicitly stated that injured individuals could only seek redress in the state tort system for certain manufacturing defect and warning

claims.

Each of the objectives extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute. The plaintiffs' construction of the statute would permit state courts to determine on a case-by-case basis whether a vaccine manufacturer could have conceivably created a safer vaccine. This would undoubtedly increase the costs and risks associated with litigation and would undermine a manufacturer's efforts to estimate and control costs. It would also effectively impose an affirmative obligation on vaccine manufacturers to pursue, regardless of cost, the countless avenues through which they could develop a safer vaccine. These were the very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act.

b.

Unfortunately, our review of legislative history does not end here. Rather than rely on the Commerce Report, the plaintiffs respond that other language in the legislative history strongly favors their position that design defect claims are not preempted. The Vaccine Act, which Congress passed in 1986, did not initially "include a source of payment for such compensation and made the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation." H.R. Rep. No. 100-391(I), at 690 (1987). In 1987, Congress passed legislation to fund

the compensation program. On October 26, 1987, as part of this funding legislation, the House Committee on the Budget ("Budget Committee") issued its own report ("Budget Report") which stated the following:

> It is not the Committee's intention to preclude court actions under applicable law. The Committee's intent at the time of considering the Act and in these amendments was and is to leave otherwise applicable law unaffected, except as expressly altered by the Act and the amendments. An amendment to establish as part of this compensation system that a manufacturer's failure to develop safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act. Further, the codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

Id. at 691.

According to the plaintiffs, this language demonstrates that Congress considered and rejected an amendment that would have explicitly preempted all design defect claims. This argument is premised on the well-settled notion that "[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442–443 (1987) (internal quotation marks and citation omitted). Additionally, plaintiffs claim that the Budget Report evidences Congress's intent to permit courts to determine on a case-bycase basis whether a vaccine's side effects were "unavoidable."

The problems with the Budget Report, however, are three-fold. First, the Budget Report repeatedly uses the term "the Committee," but it is unclear whether this refers to the Budget Committee or the Energy and Commerce Committee. While the Budget Committee did not play a role in the drafting or passage of the Vaccine Act, the Energy and Commerce Committee had jurisdiction over the bill and held several hearings on childhood vaccines and the proposed legislation. A subcommittee of the Energy and Commerce Committee also held a hearing, known as a "mark-up" hearing, on the Vaccine Act in September 1986 during which time it considered

amendments to the legislation.[11] Because the Budget Committee did not consider amendments to the Vaccine Act, we will presume that references in the Budget Report to "the Committee" refer to the Energy and Commerce Committee. Second, though the Energy and Commerce Committee conducted a mark-up hearing to consider proposed amendments, no record is available to confirm that the Energy and Commerce Committee considered and rejected an amendment related to design defects at that time.[12] Third, "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *United States v. Price*, 361 U.S. 304, 313 (1960). That danger is amply present here, where the subsequent report was not issued by the committee with jurisdiction over the legislation, but by a committee which played no role in passage of the Vaccine Act. *See United States v. United Mine Workers of Am.*, 330 U.S. 258, 281–82 (1947). Without more, we have no basis to conclude that the Budget Report is an accurate reflection of what transpired before the Energy and Commerce Committee, or for that matter, the motivations

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[11]Information pertaining to Congressional passage of the Vaccine Act, including the dates of the markup hearing and Committee consideration, can be found on the Library of Congress's website for legislative information. Library of Congress, THOMAS, S.1744 (P.L. 99-660): All Congressional Actions with Amendments, http://thomas.loc.gov/cgi-bin/bdquery/z?d099:SN01744:@@@S | TOM:/bss/d099query.html.

[12]The Energy and Commerce Committee retains a transcript of this hearing, but this transcript was not available to us.

underlying Congress's enactment of the Vaccine Act in 1986.

For these reasons, and despite plaintiffs urging, we refuse to view the relevant legislative history as containing "dueling" committee reports.

3.

Even if Congress did not intend to prohibit all design defect claims against vaccine manufacturers, the legislative history indicates that it intended to preempt the specific claim at issue here. In the days prior to passage of the Vaccine Act, the Energy and Commerce Committee issued a report containing "background information on the various issues concerning childhood vaccines . . . ." ("Background Report"). Staff of H. Comm. on Energy & Commerce, 99th Cong., *Childhood Immunizations*, at III (1986). This report stated that the pertussis vaccine "is considered the most reactive of all the commonly used vaccines and has been the one of most concern in debates over adverse effects of vaccines." *Id.* at 24. It recounted the risks and side effects associated with the pertussis vaccine, including neurological problems and even death, and the efforts of parent groups to raise awareness of these serious consequences. *Id.* at 24–29. The Background Report also stated that "research is proceeding on the effort to develop an acellular vaccine that would cause fewer side effects." *Id.* at 38. Namely, it explained that researchers were attempting to isolate the reactive components of the pertussis bacterial cell so that these components could be

excluded from the vaccine. *Id.* at 24. The Background Report also explained that Japan had used such a vaccine, but it indicated that the safety and efficacy of this vaccine had not been reported. *Id.* It then warned that "conducting clinical trials to test any new pertussis vaccine will pose major logistic, legal, and ethical problems." *Id.*

The Commerce Report on the Vaccine Act also contained numerous references to the DPT vaccine. H.R. Rep. 99-908. It noted the "serious—and sometimes deadly—consequences" of vaccines and that this was "particularly true with regard to the pertussis" component of the DPT vaccine. *Id.* at 6. Before warning of the ramifications of the withdrawal of "even a single manufacturer," the Report also highlighted the increasing number of lawsuits related to the DPT vaccine and recognized that there were only two manufacturers of the DPT vaccine at that time. *Id.* at 6–7.

Whereas the plaintiffs contend that Wyeth and its predecessors knew "for more than 25 years that the acellular vaccine was less reactogenic and, therefore, safer for the children who receive it" and seek to establish liability by virtue of that knowledge, the two reports discussed immediately above, taken together, establish that Congress intended to preempt such claims. The Background Report indicates that Congress was well aware of the state of the art concerning development of an acellular DPT vaccine. It also evidences that Congress believed there were hurdles before such a vaccine could undergo clinical

testing in the United States. The Commerce Report stresses the particular problems faced by DPT vaccine manufacturers, including the high number of lawsuits and existence of only two producers. The Commerce Report then concludes that the "withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages . . . [and] a resurgence of preventable diseases" and that the vaccine market will stabilize once "manufacturers have a better sense of their potential litigation obligations." *Id.* at 7. This evidence indicates that Congress weighed the various concerns related to the pertussis vaccine and concluded that DPT manufacturers should be shielded from liability for injuries arising from the whole-cell pertussis vaccine.

4.

As we stated at the beginning of this part, "Congressional purpose is the 'ultimate touchstone' of our inquiry." *Lorillard Tobacco Co.*, 533 U.S. at 541 (quoting *Cipollone*, 505 U.S. at 516). Section 22(a) and 22(b)(1) of the Vaccine Act contain express preemption clauses. Further, the structure and purpose of § 300aa-22 of the Act make clear that Congress intended to preempt some design defect claims. The legislative history identifies the scope of this preemption, which encompasses both strict liability and negligent design defect claims.

D.

The District Court did not clearly explain the

basis of its summary judgment decision. It neither discussed the three types of preemption nor mentioned that the motion for summary judgment raised only express preemption. Nevertheless, the District Court decision is consistent with an express preemption analysis, and we take it to have intended application of that doctrine. The four points discussed in the District Court's opinion were grounded in the purpose of the Vaccine Act. As discussed in Part III.B above, such an analysis is permitted when construing an express preemption clause. Furthermore, in response to the motion for summary judgment, the plaintiffs cited to the Vaccine Act's legislative history and purpose to support their argument that design defect claims were not preempted. As a result, we reject plaintiffs' argument that the District Court's decision was based on implied or field preemption grounds or that it violated well-settled principles of summary judgment.

IV.

Plaintiffs also allege that Wyeth is liable for failing to warn Hannah's doctor, Jane M. Breck, M.D., that the vaccine administered to Hannah came from a lot of TRI-IMMUNOL associated with at least two deaths and more than thirty injuries prior to April 1992. Dr. Breck testified that had she known that the vaccine came from this lot, she would not have administered the dose. Although § 22(c) of the Vaccine Act expressly preempts failure-to-warn claims based on "the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal

representative)," 42 U.S.C. § 300aa-22(c), nothing in the Vaccine Act expressly bars claims based on failure to warn "doctors and other medical intermediaries."[13]

As discussed above, § 22(b)(1) states that manufacturers shall not be liable for injuries caused by "side effects that were unavoidable even though the vaccine . . . was accompanied by proper directions and warnings." Section 22(b)(2) states that proper directions and warnings will be presumed when the manufacturer "complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act . . . and section 262 of this title . . . ." Nevertheless, the Vaccine Act provides two circumstances in which this presumption can be overridden: (1) when the manufacturer engages in conduct that would subject it to punitive damages under the Vaccine Act; and (2) when the manufacturer "failed to exercise due care." 42 U.S.C. § 300aa-22(b)(2)(A)-(B). As the District Court correctly noted, this creates a shifting burden—once the manufacturer establishes that it complied with federal law, the burden shifts to the plaintiff to establish that either § 22(b)(2)(A) or § 22(b)(2)(B) has been met.

The District Court dismissed this claim on the ground that Wyeth was entitled to the statutory

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[13]The parties disagree as to whether Section 22(b)(2) is a preemption clause. Though Wyeth classified it as such, the District Court expressly held that the failure-to-warn claim was not preempted. We need not reach this issue, however, for the reasons set forth in this section.

presumption of proper warning and that the plaintiffs had failed to rebut the presumption. Noting that Wyeth had presented uncontested evidence that TRI-IMMUNOL and its warnings had been approved by the FDA, the District Court found that Wyeth was entitled to § 22(b)(2)'s presumption of proper warning. Next, the District Court noted that the Amended Complaint did not allege fraud or wrongful withholding of information within the meaning of § 22(b)(2)(A).[14] Thus, the only relevant question was whether plaintiffs had presented clear and convincing evidence that Wyeth had not exercised due care.

Plaintiffs presented a report of the Vaccine Adverse Event Reporting System ("VAERS")[15] confirming that the lot of TRI-IMMUNOL that included the dose administered to Hannah Bruesewitz was associated with two deaths and more than thirty injuries. They also presented the affidavit of Dr. Donald H. Marks, who claimed that such a lot is sometimes called a "hot lot." Dr. Marks relied on a

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[14]The District Court acknowledged that the original Complaint alleged that Wyeth had committed fraud or wrongful withholding of information, but the Amended Complaint failed to do so. Nevertheless, even if the Amended Complaint had repeated this allegation, the District Court suggested that it would not have survived application of Fed. R. Civ. P. 9(b), which requires that allegations of fraud be pled with particularity.

[15]As the District Court explained, "VAERS is a database created, pursuant to the Vaccine Act, by the FDA and the Centers for Disease Control and Prevention to receive reports about adverse events which may be associated with vaccines."

1984 memorandum by an epidemiologist at the Department of Health and Human Services ("HHS") regarding the "Investigation of Potential Hot Lots," which said that "potential hot fill lots of DTP vaccine" are "fill lots that exceeded a threshold of ≥2 deaths or ≥2 convulsions or ≥10 total reports." The District Court, however, found it significant that this memorandum identified such lots merely as "potential" hot lots.

The memorandum also stated that "[i]n order to proceed with an investigation by which we could differentiate reporting bias from a higher rate of reactivity in specific fill lots we needed information on the number of doses distributed and which percent went to the public sector." Thus, in order to differentiate between a "hot lot" and a "potential hot lot," investigators must know not only the total number of incidents but also the rate at which the incidents occurred. Because the "[p]laintiffs have produced no evidence from which a trier of fact could infer that the dose in question originated" in such a lot, the District Court concluded that the plaintiffs had not proven that Wyeth failed to exercise due care by distributing doses from this lot.

Before this Court, the plaintiffs argue that the District Court's reasoning is flawed on two grounds: (1) Wyeth is not entitled to a presumption of proper warning unless the side effects of the vaccine are first shown to be unavoidable; because they allege a safer vaccine design was available, they argue that § 22(b)(2) should not apply; and (2) Dr. Mark's opinion

raises an issue of fact as to whether Hannah's dose came from a "hot lot." We dismiss both arguments. The first argument must be dismissed for the reasons discussed in Part III—the Vaccine Act preempts design defect claims premised on the notion that the manufacturer could have created a safer vaccine. The second requires more discussion.

As stated above, a court may not grant summary judgment so long as there exists a genuine issue of material fact. Fed. R. Civ. P. 56(c); *Kaucher v. County of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006). To determine whether a factual dispute is genuine, "the court's function is not to weigh the evidence or to determine the truth of the matter, but only to determine whether the evidence of record is such that a reasonable jury could return a verdict for the nonmoving party." *Orsatti v. N.J. State Police*, 71 F.3d 480, 482 (3d Cir. 1995); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The "mere existence of a scintilla of evidence" in support of the nonmoving party's claim is insufficent. *Anderson*, 477 U.S. at 252. We will resolve all doubts and draw all reasonable inferences in favor of the nonmoving party. *Conoshenti v. Pub. Serv. Elec. & Gas Co.*, 364 F.3d 135, 140 (3d Cir. 2004).

Dr. Marks identified the HHS memorandum as the basis on which he drew his conclusions: "This memorandum provides what I understood to be the

official definition of a 'Hot Lot'."[16] As the District Court correctly noted, the memorandum clearly states that the incident statistics, cited above, only establish "potential hot lots." It further states that investigators must identify the number of doses administered to determine whether a particular vaccine lot qualifies as a "hot lot."[17] Because plaintiffs have not offered any

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[16]Dr. Marks also approvingly cited to an older document from the Food and Drug Administration. This document states:

> In analyzing patterns of adverse event reporting, the FDA considers more than just the number of reports for a lot. More reports will be received for a large lot than a small one, simply because vaccine from the large lot will be given to more children. Some lots contain as many as 700,000 doses, while others as few as 20,000 doses. Similarly, more reports will be received for a lot that has been in use for a long time than a lot in use for a short time. Even among lots of similar size and time in use, some lots will receive more reports than others simply due to change. The FDA continually looks for lots that have received more serious reports tha[n] should be expected on the basis of such factors as size, time in use, and chance variation.

Pub. Health Serv., Dep't of Health & Human Servs., *Vaccine Adverse Event Reporting System (VAERS)* 2.

[17]Other authorities support this. For instance, according to the Centers for Disease Control and Prevention:

> Vaccine lots are not the same. The sizes of vaccine lots might vary from several hundred thousand doses to several million, and some are in

evidence on this point, Dr. Marks' assertions and conclusions are unsupported by the very memorandum upon which he relies.

The plaintiffs also contend that the sheer number of adverse events associated with this vaccine lot is sufficient to establish "some evidence of a serious health problem no [matter] how many doses, circumscribed by the concept of a batch, it contains." While this may be true, the plaintiffs' burden is not to produce "some evidence"—a mere scintilla—but evidence sufficient for a reasonable jury to find in their favor. The HHS memorandum states that investigators cannot conclude whether a vaccine lot is a "hot lot" without evidence on the number of doses administered. Thus, even drawing all inferences and doubts in favor of the plaintiffs, there is insufficient

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> distribution much longer than others. Naturally a larger lot or one that is in distribution longer will be associated with more adverse events, simply by chance. Also, more coincidental deaths are associated with vaccines given in infancy than later in childhood, since the background death rates for children are highest during the first year of life. So knowing that lot A has been associated with x number of adverse events while lot B has been associated with y number would not necessarily say anything about the relative safety of the two lots, even if the vaccine *did* cause the events.

Centers for Disease Control and Prevention, Some Common Misconceptions About Vaccination and How to Respond to Them, http://www.cdc.gov/vaccines/vac-gen/6mishome.htm#Therearehot.

evidence on which a jury could conclude that Hannah's vaccine came from a "hot lot." Accordingly, the District Court did not err in granting summary judgment on the failure to warn claim.

V.

In their Amended Complaint, the plaintiffs alleged that Wyeth's "manufacturing process and inadequate quality control resulted in recurrent problems with maintaining the appropriate balance between neuron-toxins and endo-toxins in the pertussis vaccine." Plaintiffs also assert, as they do before this Court, that they have a "classic manufacturing defect claim here: that the vaccine lot used on Hannah Bruesewitz was tainted such that it was associated with two deaths and more than 66 injuries, a number and percentage far in excess of that for other lots." Under Pennsylvania law, a plaintiff alleging a manufacturing defect based on a strict liability theory must show that: (1) "the product was defective;" (2) "the defect was a proximate cause of the plaintiff's injuries;" and (3) the defect causing the injury existed at the time the product left the seller's hands." *Berkebile v. Brantly Helicopter Corp.*, 337 A.2d 893, 898 (Pa. 1975).

The District Court held that plaintiffs had failed to provide enough evidence of a manufacturing defect to meet their burden for purposes of summary judgment. With regard to the first claim, related to the balance of neuro- and endo-toxins, the District Court concluded that "Plaintiffs have offered absolutely no

evidence to support this allegation . . . ." Moreover, the District Court noted this claim was directly refuted by Wyeth, which offered undisputed evidence that its pertussis vaccine did not contain a neuro-toxin component and was not known to have a neuro-toxic effect.

The District Court also considered the plaintiffs' second argument, which was essentially the same as the "hot lot" theory discussed above. The plaintiffs argued to the District Court that a "hot lot" can serve as circumstantial evidence of a manufacturing defect. The District Court noted that this theory is known as the "malfunction theory:"

> The malfunction theory permits a plaintiff to prove a defect in a product with evidence of the occurrence of a malfunction and with evidence eliminating abnormal use or reasonable, secondary causes for the malfunction. The plaintiff is relieved from demonstrating precisely the defect yet it permits the trier-of-fact to infer one existed from evidence of the malfunction, of the absence of abnormal use and of the absence of reasonable secondary causes.

Bruesewitz v. Wyeth, 508 F. Supp.2d 430, 450 (E.D. Pa. 2007) (quoting *Barnish v. KWI Bldg. Co.*, 916 A.2d 642, 646 (Pa. Super. Ct. 2007)).

As the District Court recognized, this theory has

not been applied to allegedly defective vaccines. Nevertheless, we need not determine if and how this theory of liability would apply in this case. Both before the District Court and this Court, the plaintiffs predicated their argument for a manufacturing defect on the fact that Hannah's vaccine came from a "hot lot." For the reasons stated in Part IV, after drawing all reasonable inferences in favor of the plaintiffs, we agree with the District Court's conclusion that the plaintiffs have not provided evidence from which a jury could conclude that Hannah was administered a vaccine from a "hot lot." Because plaintiffs sole arguments to this Court on the manufacturing defect issue require a finding of a "hot lot," we will also affirm the District Court's judgment on this claim.

VI.

We hold that the plaintiffs design defect claims are expressly preempted by the Vaccine Act. We also conclude that the plaintiffs have failed to establish either a manufacturing defect or a warning defect claim under the Vaccine Act. For the reasons discussed above, we will affirm the District Court's grant of summary judgment in favor of Wyeth.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

BRUESEWITZ, et al.,
Plaintiffs,

v.

Civil Action
NO. 05-5994

WYETH, INC.,
Defendant.

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ILLEGIBLE]

MEMORANDUM

Baylson, J.

August 24, 2007

I. Introduction

Presently before the Court are Defendant's Motions for Summary Judgment (Doc. Nos. 22, 73, 88) in this products liability suit, on the grounds that: (1) the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 *et seq.*, preempts tort claims for the allegedly defective design of a vaccine under § 300aa-22(b)(1) of the Act; (2) § 22(c) bars Plaintiffs' failure-to-warn claim; and (3) as to any claims not preempted by the Vaccine Act, there are no genuine issues of fact for trial. For the reasons set forth below, the Court finds Counts I and III fo the Amended Complaint are

preempted by the Vaccine Act, and that Plaintiffs have failed to raise any genuine issue of material fact as to Counts II and IV. Accordingly, Defendant's Motions will be GRANTED.

II. Background

A. Procedural Background

On April 3, 1995, Plaintiffs filed a petition in the United States Court of Federal Claims seeking compensation as provided by the Vaccine Act. 42 U.S.C. § 300aa-1 *et seq.* On February 14, 2003, Plaintiffs rejected the judgment of the Vaccine Court. These proceedings followed. Plaintiffs initially filed their Complaint in the Philadelphia County Court of Common Pleas in October, 2005. Defendant removed the case to this Court based on diversity of citizenship, and filed a first Motion for Summary Judgment (Doc. No. 22). Plaintiffs filed their Response (Doc. No. 29), and Defendants timely replied (Doc. No. 32).

This defense motion was based on Wyeth's contention that Plaintiffs' claims were preempted. The Court considered this motion as premature since little, if any, discovery had taken place and eventually denied this motion without prejudice, by Order dated February 22, 2007.

The parties engaged in extensive discovery, and the Court held several unrecorded pretrial conferences. The Court expressed some confusion

over the nature of Plaintiffs' claims, and on January 23, 2007, required Plaintiffs to serve a contention statement listing Plaintiffs' claims in more detail. An Amended Statement of Contentions was filed by Plaintiffs on February 1, 2007 (Doc. No. 55).

The Court again noted, in its Memorandum and Order of February 22, 2007, that although Plaintiffs were making a claim of negligence for a manufacturing defect, Plaintiffs had not yet specifically alleged a claim for strict liability based on manufacturing defect, and held that such a claim would not be encompassed within the negligence cause of action asserted in the original Complaint. Although Plaintiffs had not sought leave to file an amended complaint, the Court suggested Plaintiffs move to amend their Complaint if they wished to proceed to trial on a strict liability claim relating to manufacturing. Plaintiffs did file a Motion for Leave to file a First Amended Complaint on March 7, 2007 (Doc. No. 67). On March 9, 2007, the Court entered an Order requiring briefing on Plaintiffs' Motion for Leave to File an Amended Complaint, discussing the impact of the claims presented in the Motion to Amend (and specifically the new claim based on strict liability for manufacturing defect) in the context of the preemption issues already briefed. As noted in the Order, Plaintiffs' counsel had advised the Court that Plaintiffs would not require any additional discovery if the amendment was allowed, but Defendant's counsel reserved the right to pose contention interrogatories. The Court directed any fact discovery should be completed by April 5, 2007.

The Court designated briefs previously filed on certain issues to be considered as supporting Defendant's legal position that Plaintiffs' claims were preempted, or alternatively, that Plaintiffs had failed to raise a genuine issue of material fact requiring a trial.

By Memorandum and Order dated April 18, 2007, the Court reviewed the procedural history of the case, and although noting Wyeth's objection to the Amended Complaint, particularly the claim of strict liability for manufacturing defect, the Court stated it would allow Plaintiffs to add a count for strict liability for manufacturing defect "to give Plaintiffs an opportunity to show that there is factual support to show a genuine issue for trial on the claim that there was a manufacturing defect in the specific lot or lots of vaccine administered to the Plaintiffs' minor." The Amended Complaint became the operative statement of Plaintiffs' claims.

The Court again gave leave for additional discovery, and entered a schedule for the completion of the briefing on the pending defense Motions for Summary Judgment. Defendant asserts that all four Counts of the Amended Complaint are preempted by the Vaccine Act, or in the alternative, that Plaintiff has failed to raise any questions of material fact, warranting summary judgment pursuant to Fed. R. Civ. P. 56.

B. Factual Background

Pursuant to the Court's standard practice, Defendant filed Statements of Undisputed Facts (Doc. Nos. 22, 88) to which Plaintiffs responded (Doc. Nos. 29, 95). From Defendant's statements of fact and Plaintiffs' counter-statements, the Court establishes the following facts which are not in dispute:

Minor Plaintiff, Hannah Bruesewitz, received her third diphtheria-pertussis[1]-tetanus ("DPT") vaccine in April, 1992. (Def's First Statement of Undisputed Facts ¶ 1; *see also* Pl's Resp. to Def's First Statement of Undisputed Facts ¶ 1.) At the time of this vaccination, the Advisory Committee on Immunization Practices recommended administration of the DPT vaccine five times, at approximately 2, 4, 6 and 15-18 months, and 4-6 years of age. (*Id.* ¶ 2.) Born on October 20, 1991, Hannah received the first three doses of the DPT vaccine according to this recommendation. (*Id.* ¶¶ 3-4.) After her third vaccination, Hannah suffered a seizure, and was subsequently diagnosed with "residual seizure disorder" and "developmental delay." (*Id.* ¶ 5.)

Defendant's DPT vaccine administered to Hannah (trade name, TRI-IMMUNOL®) contained whole, killed pertussis cells (the "whole-cell" vaccine). (*Id.* ¶ 6.) The National Health Institute

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[1]Pertussis is the disease also commonly known as whooping cough.

first issued a product license to American Cyanamid Company ("Cyanamid") in 1948 for TRI-IMMUNOL®, which was produced by Lederle Laboratories, an unincorporated division of Cyanamid. (Def's Second Statement of Undisputed Facts ¶¶ 13,19.) In 1994 American Home Products Corporation ("AHPC") acquired Cyanamid. (*Id.* ¶ 15.) From 1948 until 1998, when AHPC voluntarily discontinued the manufacture of TRI-IMMUNOL®, Cyanamid, and after 1994, AHPC, held a valid product license for TRI-IMMUNOL®. (*Id.* ¶ 19.)

At the time of Hannah's vaccination, the Food and Drug Administration ("FDA") had already approved Defendant's application for an alternative DPT vaccine (trade name, ACEL-IMUNE®) that contained "an acellular pertussis component." (Def.'s First Statement of Undisputed Facts, ¶ 7.) The FDA's approval at that time only allowed Defendant to distribute ACEL-IMUNE® for the fourth and fifth doses in the DPT vaccination series. (*Id.* ¶ 8.) The FDA approved the first acellular pertussis vaccine for use in the first three doses of the vaccination series on July 31,1996 (*id.* ¶¶ 9, 10); ACEL-IMUNE® did not obtain such approval until December 1996 (*id.* ¶ 11).

C. Allegations in the Amended Complaint

Although the Amended Complaint purports to restate the claims of the original Complaint, the Court regards the Amended Complaint as the operative statement of Plaintiffs' claims. The

Amended Complaint proceeds with four counts. Count 1 alleges Wyeth negligently failed to produce a safer vaccine despite knowledge of the existence and feasibility of such safer alternatives. (Am. Compl. ¶¶ 32-34.) Count II alleges Wyeth negligently failed to warn of the actual dangers associated with the particular batch DPT vaccine administered to Hannah Bruesewitz. (*Id.* ¶ 35) Count III asserts strict liability for design defect, in that the existence or feasibility of safer alternative designs for the vaccine rendered the vaccine administered to Hannah defective and unreasonably dangerous. (*Id.* ¶ 36.) Count IV asserts strict liability for manufacturing defect, in that, in addition to the unreasonable danger due to the aforementioned alleged design defect, the particular dose of vaccine administered to Hannah contained a manufacturing defect that made it "extra-hazardous." (*Id.* ¶ 37.) Plaintiffs are suing for damages to Hannah Bruesewitz, costs, punitive damages, and other legal or equitable relief the Court deems just and proper. (*Id.* ¶¶ 38-41.)

III. Parties' Contentions[2]

A. Defendant

Defendant's Motions for Summary Judgment claim the Vaccine Act precludes all of Plaintiffs'

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[2]Both parties have filed multiple briefs on Defendant's three summary judgment motions. This summary draws from all the briefs submitted by the parties.

claims. As to Count I Defendant contends the negligence allegations in the Complaint must be construed as a design defect claim. According to Defendant, the plain language of the Vaccine Act reflects the intent of Congress to preempt state law claims for design defects. Defendant argues that this is a broad immunity, not subject to case-by-case review in the courts, mandating dismissal of Counts I and III.

Defendant maintains the Vaccine Act also explicitly bars the failure-to-warn claim in Count II. Defendant points out that the Act provides immunity from suit for failure to warn when the suit is based on a failure to warn directly any member of the general public. Wyeth further argues it is entitled to a presumption that the warnings accompanying the vaccine in question were proper as a matter of law, and Plaintiffs cannot produce any evidence to overcome that presumption, entitling it to immunity from suit for failure-to-warn under the Vaccine Act.

As to Count IV, Wyeth first argues Plaintiffs have not actually pleaded a manufacturing defect, but rather a design defect, in that the flaws alleged to exist in the vaccine administered to Hannah represent differences in the reactivity among different batches of the vaccine, inherent in the design of the whole-cell pertussis vaccine. According to Wyeth, allowing Count IV to go forward would, in essence, allow the very case-by-case review of vaccines it claims the Vaccine Act preempts.

Alternatively, Wyeth offers arguments in favor of summary judgment addressing the merits of Plaintiffs' claims. First, Wyeth argues that no genuine issue of material fact exists as to Count I of the Amended Complaint because Wyeth did not act unreasonably as a matter of law in marketing an FDA-approved vaccine. Defendant asserts no alternatively designed DPT vaccine existed at the time Hannah Bruesewitz received TRI-IMMUNOL® which was also approved for use on a child of Hannah's age.

As to Count II, Wyeth contends the failure-to-warn claim must also fail as a matter of law because Wyeth warned of the exact adverse event which allegedly befell Hannah Bruesewitz.

Further, Wyeth asserts that theories of strict liability are inapplicable to claims involving prescription drugs, requiring dismissal of Counts III and IV of the Complaint as a matter of Pennsylvania state law. Wyeth finally contends Plaintiffs have not met the burden of establishing facts sufficient to warrant a trial on the claim of a manufacturing defect because the evidence is insufficient to allow a jury to find the vaccine Hannah Bruesewitz received failed to meet its intended design specifications in any way.

2. Plaintiffs

Plaintiffs' view of Vaccine Act preemption arises from a fundamentally differing interpretation

of the Act's plain meaning and congressional intent than espoused by Defendant. Plaintiffs first assert that a textual interpretation of the Act does not support preemption of all design defect claims. Plaintiffs contend that, by only preempting state tort law for "unavoidable" harms, Congress left it to courts applying state law to determine this issue of avoidability on a case-by-case basis, and then adjudicate claims arising from avoidable harms; only if a court found that the harm suffered by a specific individual was "unavoidable," would preemption apply. Plaintiffs point out that the Vaccine Act could have, but does not, explicitly bar claims for design defects. Plaintiffs contend that such a drastic reduction in the purview of state tort systems should not be inferred when Congress could have so easily made it clear.

According to Plaintiffs, while the Act was clearly meant to limit vaccine manufacturers' exposure to liability, Congress never intended to preclude injured parties from pursuing claims in tort. In Plaintiffs' view, Congress has encouraged vaccine manufacturers to continue producing vaccines by granting protection from lawsuits based on injuries caused by unavoidable side effects; however, Plaintiffs maintain that Congress also intended state tort systems to act partly as a goad to encourage further innovation and improvements of vaccines. Vaccine manufacturers continue to be liable for avoidable side effects; avoidability must be determined on a case-by-case basis. Plaintiffs argue that prior, factually similar cases were incorrectly

decided. Specifically regarding Count II, Plaintiffs contend Wyeth has attempted to mischaracterize the warnings supplied with the vaccine as part of the vaccine's design, thereby avoiding the fact that failure-to-warn claims are ordinarily not preempted under the Vaccine Act.

On the merits of their design defect claims, Plaintiffs argue that the existence of safer alternatives to TRI-IMMUNOL® rendered the design of that vaccine defective. In their Further Statement of Undisputed Facts, Plaintiffs aver Wyeth bought the license for an alternative, "noncellular" DPT vaccine, TRI-SOLGEN, but never marketed the drug. (Pl's Further Statement of Undisputed Facts ¶¶ 1-3, 7, 8.) Defendant does not dispute this fact, but contends it is irrelevant.

Plaintiffs urge against dismissal of Count II, arguing Wyeth is not entitled to the presumption of adequate warnings because Wyeth has not yet established that its product was unavoidably unsafe.

In support of their manufacturing defect claims at Counts I and IV Plaintiffs suggest the proper definition of a manufacturing defect compares the allegedly defectively manufactured product to a perfectly manufactured product of the same product line. According to Plaintiffs, this analysis establishes a manufacturing defect in that Wyeth knew a certain number of adverse reactions occurred in each lot of vaccine. Plaintiffs contend that Defendant's decisions about quality control are not a design

defect, but rather reflect Defendant's willingness to allow a certain number of defectively manufactured vaccine lots be administered to patients. As such, Plaintiffs claim the evidence shows Hannah received a dose of vaccine from a lot associated with at least two deaths and more than 66 injuries (Pl's Further Statement of Undisputed Facts, ¶ 4), and they have therefore established sufficient facts from which a jury could reasonably conclude she received vaccine from a defectively manufactured lot. In a final twist, Plaintiffs challenge Defendant's state-law defenses, contending the Vaccine Act preempts any state laws which limit the rights of vaccine recipients to sue for any reason not barred by the Act.

IV. Legal Standard

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). An issue is "genuine" if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248,106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). A factual dispute is "material" if it might affect the outcome of the case under governing law. *Id.*

A party seeking summary judgment always bears the initial responsibility for informing the

district court of the basis for its motion and identifying those portions of the record that it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party's initial burden can be met simply by "pointing out to the district court that there is an absence of evidence to support the non-moving party's case." *Id.* at 325. After the moving party has met its initial burden, "the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial." FED. R. CIV. P. 56(e). Summary judgment is appropriate if the non-moving party fails to rebut by making a factual showing "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322. Under Rule 56, the Court must view the evidence presented on the motion in the light most favorable to the opposing party. *Anderson*, 477 U.S. at 255.

V. Discussion

A. Vaccine Act

The legislative history of the Vaccine Act describes the creation of "a new system for compensating individuals who have been injured by vaccines routinely administered to children." H.R. Rep. No. 99-908 (1986), *reprinted in* 1986

U.S.C.C.A.N. 6344. The new system, the NVICP, includes a streamlined adjudication process in which the injured recipient of a vaccine (or the injured party's legal representative) brings a claim in the United States Court of Federal Claims. The claimant receives compensation if it can be shown that the injured party (1) received a vaccine covered by the Act, (2) suffered injuries associated with that vaccine, and (3) it cannot be shown by a preponderance of the evidence that the injuries were not caused by the vaccine. 42 U.S.C. § 300aa-13.

The NVICP came about, in part, due to the inadequacy of state common law tort systems to provide either relief to injured children and their families, or predictable standards of liability to vaccine manufacturers. H.R. Rep. No. 99-908 at 7. On the one hand, claims brought against vaccine manufacturers by the parents of injured children required large amounts of time and money for an uncertain result. *Id.* at 6. On the other hand, manufacturers were also burdened by the time and expense of litigation. Although most cases ended favorably for the manufacturers, the extremely large sums returned by some juries, and the increased number of suits, meant that liability insurance was no longer affordable. *Id.* at 7. As a result many pharmaceutical manufacturers had left, or intended to leave, the childhood vaccine market. *Id.*

The NVICP is a streamlined, "no-fault" compensation scheme in which injured vaccine recipients recover damages without showing

"causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective." *Id.* at 12. The House Committee Report anticipated the NVICP would divert "a significant number of potential plaintiffs from litigation" due to the system's speed, low transaction costs, no-fault nature, and the relative certainty and generosity of the system's rewards. *Id.* at 13. The Report noted that many people without any remedy under state tort laws would also be compensated by the NVICP.

Thus, the NVICP is meant to help maintain the national vaccine supply, both by ensuring compensation to injured children and their families, as well as by providing vaccine manufacturers with an affordable and predictable way of handling such compensation so as to allow them to continue to profitably make vaccines. *Id.*

In addition to creating this new compensation scheme, the Vaccine Act limits injured parties' remedies in tort. *See* 42 U.S.C. § 300aa-22; H.R. Rep. No. 99-908. Informed by the Restatement (Second) of Torts § 402A comment k,[3] the Vaccine Act holds

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[3]Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariable leads to a

vaccine manufacturers immune from liability "if the injury or death resulted from side effects that were *unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (emphasis added).

The major legal issues before the Court relate to section 22 of the Vaccine Act: (1) whether subsection 22(b)(1) presents a complete bar to design defect claims; (2) whether Plaintiffs have complained of a failure to warn that is not protected by the Act; and (3) whether Wyeth's defenses based in Pennsylvania state law are preempted by subsection

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dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally by sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. Restatement (Second) of Torts § 402A cmt. k (1965).

22(c). Section 22 of the Vaccine Act provides, in relevant part:

> (a) General Rule. Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
> (b) Unavoidable adverse side effects; warnings.
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after Oct. 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
> (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 *et seq.*] and section 262 of this title (including regulations under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows–
>
> > (A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of

this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings. No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after Oct. 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

. . . .

(e) Preemption. No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle [42 U.S.C. §§ 300aa-10 *et seq.*].

42 U.S.C. § 300aa-22.

B. Design Defect Claims Under the Vaccine Act[4]

1. Prior Rulings Upholding Vaccine Act Preemption

To date, analogous cases which required a ruling as to whether the Vaccine Act bars claims for design defects have been decided by two intermediate state appellate courts and two federal district courts. All but one have held the Vaccine Act preempts design defect claims, including Judge Stengel in this District. The reasoning in each of the three cases is very similar. The first federal ruling is *Blackmon v. American Home Products Corp.*, 328 F. Supp.2d 659 (S.D. Tex. 2004). The court granted defendants' motion for partial summary judgment, holding the Vaccine Act entirely bars injured vaccine recipients from claiming a design defect under state tort law. *Id.* at 666. The court only partially granted summary judgment of plaintiffs' failure-to-warn claim. *See id.* at 666-67.

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[4]The Vaccine Act limits a manufacturer's liability for design defects regardless of the cause of action. Therefore, the analysis below applies equally well to Plaintiffs' negligence claim at Count I and their strict liability design defect claim at Count III. *Sykes v. GlaxoSmithKline*, 484 F. Supp. 2d 289, 303 (E.D. Pa. 2007) ("The text of the Vaccine Act that limits a manufacturer's liability is not directed toward any particular cause of action."); *Blackmon v. American Home Products Corp.*, 328 F. Supp. 2d 659, 666 (S.D. Tex. 2004) ("The phrase 'a civil action for damages' encompasses products liability claims based on negligence as well as those based on strict liability. While comment k is restricted to strict liability claims, § 22(b) is not.")

In *Blackmon*, parents sued on behalf of their child who suffered neurological disorders as a result of the mercury preservative (thimerosal) used in the vial containing a vaccine administered to the child. The parents' theory of liability was that the vaccine was not unavoidably unsafe because thimerosal was only used in multi-dose vials. If the vaccine manufacturers had provided single-dose vials, no preservative would have been necessary, and their child would not have suffered any injuries. 328 F. Supp.2d at 663.

Defendants argued § 22(b)(1) totally preempts state law, constituting a complete bar to design defect claims for any vaccine approved by the FDA. The plaintiffs countered that whether the drug was unavoidably unsafe should be determined on a case-by-case basis under state law, requiring a jury to determine the merits of their alternate design theory, the single-dose vial that contains no preservative, in spite of the FDA's approval of defendants' vaccine. *Id.*

Relying on the legislative history, the court concluded the policy of the Vaccine Act is to protect the national vaccine supply by protecting manufacturers from the potential inconsistencies of the 50-state tort system, while still providing parents with a remedy should their child be harmed by a vaccine. *See id.* at 665 ("The last passage [of the legislative history] indicates rather clearly the Committee's intent to relegate design defect claims

to the compensation system, provided that the injury-producing vaccine was manufactured and distributed according to applicable federal standards.")

The court compared § 22(b)(1) to the Restatement (Second) of Torts § 402A cmt. k, finding that Congress intended to incorporate the comment's liability principles into the Vaccine Act. *Id.* at 664. The court's interpretation of comment k led it to conclude that, without a complete bar to design defect claims, § 22(b)(1) would be stripped of all meaning. *Id.* at 665. In the court's view, defects that are "truly unavoidable in the broad, literal sense" would render claims meritless to begin with, thus leaving no need for congressional protection. *See id.* In the court's view, allowing a case-by-case determination of unavoidability would undercut not only the protections the Vaccine Act provides vaccine manufacturers, but also the broader, "comprehensive regulatory scheme, administered by the FDA, to control the design and distribution of prescription drugs, including vaccines." *Id.* at 665.

Finally, the court concluded the Vaccine Act makes no distinction between theories of liability based on strict liability or negligence. While acknowledging that comment k only applies to strict liability in the Restatement, the court noted that § 22(b)(1) granted immunity in "a civil action for damages," thus encompassing both theories of liability. *Id.* at 666.

Since *Blackmon*, Judge Stengel of this Court made a similar ruling in *Sykes v. GlaxoSmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007). In *Sykes* the plaintiffs asserted strict products liability and negligence against three pharmaceutical companies for alleged injuries to the minor plaintiff, Wesley Sykes, claiming, in part, that defendants' products were defectively designed and that safer alternatives existed at the time the drugs were administered. *Id.* at 294. As in *Blackmon*, the plaintiffs alleged injuries to the minor plaintiff resulted from a negative reaction to the mercury preservative thimerosal used in the vaccines administered to him. *Id.*

Upon the defendants' motion to dismiss, Judge Stengel held, "the plaintiffs' defective design claims against [the vaccine manufacturer defendants], based on a strict liability theory, are barred." *Id.* at 301. The court, largely adopting the reasoning in *Blackmon*, based its ruling on four basic conclusions: (1) the purpose of the Vaccine Act to protect vaccine manufacturers from the unpredictability and expense of the tort system would be thwarted by allowing juries to decide design defect claims by evaluating whether a vaccine was unavoidably unsafe on a case-by-case basis; (2) through the Vaccine Act, Congress delegated to the Department of Health and Human Services, rather than the jury system, the role of assuring improvements in the quality, effectiveness, and safety of vaccines; (3) the Vaccine Act protects manufacturers from design defect claims in

particular; and (4) comment k supports the understanding that the liability of vaccine manufacturers is limited to claims that the vaccine deviated from its FDA-approved design. *Sykes*, 484 F. Supp. 2d at 301-03. The court further found Vaccine Act preemption applies to claims for both negligence and strict liability. *Id.* at 303.

Intermediate appellate courts in two states have disagreed on the preemption issue. Upholding a trial court's grant of summary judgment in favor of vaccine manufacturers in *Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006),[5] the court held, "Congress' intent in enacting the prohibition on civil actions by the Vaccine Act was to adopt by reference Restatement (Second) of Torts § 402A, comment k." *Id.* at 508. While recognizing that the discussion of comment k in an early portion of the Committee Report leaves open the possibility of design defect claims, the court found a later section foreclosed that option. *Id.* The later section states,

> Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate

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[5]The trial court's decision in *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839 (N.Y. Sup. Ct. 2003), is the first ruling by any court on Vaccine Act preemption of design defect claims.

> warnings [they] should pursue recompense in the compensation system, not the tort system.

H.R. Rep. No. 99-908 at 508. Noting "[p]reemption is a question of Congressional intent," Militrano, 810 N.Y.S.2d at 477 (*citing California Fed. Sav. & Loan Assn. v. Guerra*, 479 U.S. 272, 280 (1987)), the court found Congress clearly intended to preclude all design defect claims with respect to vaccines covered by the Vaccine Act. *Id.*

2. The Ruling Rejecting Preemption[6]

In the trial court opinion in *Ferrari v. Amer. Home Products Corp.*, No. 02-VS-031404-F, slip op., 7-8 (Sup. Ct. Fulton Co. Nov. 30, 2005), it was the *plaintiffs* who argued Congress had simply incorporated comment k into § 22(b)(1). Although the court disagreed with the plaintiffs' contention on this point, it considered its ruling in accord with *Blackmon*. *Id.* at 8.

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[6]Plaintiffs point to *Mazur v. Merck & Co.*, 742 F. Supp. 239 (ED. Pa. 1990), as precedent from this District rejecting preemption. In *Mazur*, Judge Ditter found, "Pennsylvania tort law is not preempted by federal regulation of vaccine manufacture, distribution, and labeling, in general." 742 F. Supp. at 248. Wyeth has conceded that manufacturing claims and certain failure-to-warn claims are not preempted by the Vaccine Act. *Mazur* is inapposite to the context in which Plaintiffs cite it, as it does not address design defect claims.

The court reasoned that plaintiffs' reading of comment k and the Vaccine Act would be correct if § 22(b)(1) exempted injuries resulting from "side effects that were unavoidable," but since the exemption is for "side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings," plaintiffs' interpretation did not account for all the elements of the statute. *Id.* (emphasis in original). The court found, "By its express terms, the statute immunizes vaccine manufacturers from liability for side effects that inevitably occur even though a vaccine is properly prepared in every respect according to its approved design specifications and is properly labeled," *id.*, thereby adopting the same understanding as in *Blackmon* that FDA approval defines what vaccines are unavoidably unsafe.

The Court of Appeals of Georgia overturned the above ruling in a unanimous decision. *Ferrari v. American Home Products Corp.*, No. A07A0306, 2007 WL1933129 (Ga. Ct. App. July 5, 2007). The court based its opinion on an admittedly novel application of *Bates v. Dow Agrosciences LLC,* 544 U.S. 431 (2005), to § 22(b), acknowledging that none of the previous courts to address this issue had considered *Bates*. 2007 WL 1933129, at *3. According to the Court of Appeals of Georgia, if a preemption statute is ambiguous, Bates requires a court to adopt the reading that disfavors preemption. *Id.* at *4. The Georgia court noted its accord with

Sykes[7] and *Militrano*[8] in that § 22(b) is ambiguous as to whether injuries are, "'unavoidable' and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings ... [or whether] design defect claims are preempted only if the side-effects are determined to be unavoidable on a case-by-case basis." *Ferrari*, 2007 WL 1933129, at *4. Although the court agreed with all the previous courts' findings as to congressional intent, it held that *Bates* required it to apply the interpretation disfavoring preemption, notwithstanding that intent. *Id.* ("We recognize that this result is anomalous given the clear legislative history to the contrary, but we are constrained to follow the Supreme Court's explicit guidance in Bates.") The Georgia court therefore remanded the case for proceedings as to whether the vaccine was unavoidably unsafe.

a. Bates does not alter the preemption analysis of the Vaccine Act

Bates is a recent Supreme Court case addressing the scope of the preemption provision in the Federal Insecticide, Fungicide, and Rodenticide

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[7] *See* 484 F. Supp. 2d at 308-309.

[8] *See* 769 N.Y.S.2d at 843-844.

Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*[9] Plaintiffs brought claims against the defendant, a pesticide manufacturer, when their peanut harvest was damaged by use of the defendant's pesticide in alkaline soil despite the pesticide label claiming its appropriateness for use anywhere peanuts are grown. *Bates*, 544 U.S. at 435-36. The Fifth Circuit upheld the district court's finding of preemption, reasoning that the plaintiffs' tort claims, if successful, would induce the defendant to change its label. *Id.* at 436. In overruling, the Supreme Court first noted, "FIFRA [is] not a sufficiently comprehensive statute to justify an inference that Congress had occupied the field to the exclusion of the States." *Id.* at 441-42 (internal quotations omitted). Next, it held, "Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense." *Id.* at 442. Finally, the Court found the ban on states imposing a "requirement" did not preempt the creation of an "inducement." *Id.* at 445. The plaintiffs' claims were for defective design, as well as violation of an express warranty, rather than a defective warning label. *Id.* at 444. The Court reasoned the duties imposed by such common law rules might induce the pesticide manufacturer to change its labeling; however, an adverse jury verdict would not require

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[9]The preemption provision states, "[States] shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b).

the manufacturer to change. *Id.* at 445. As such, design defect claims at common law are not preempted by the express language of the FIFRA preemption provision. The Supreme Court found, however, the plaintiffs' alleged fraud and failure-to-warn claims to be preempted, since those claims were "premised on common-law rules that qualify as 'requirements for labeling or packaging.'" *Id.* at 446. In this way, the Supreme Court adopted a "parallel requirements" reading of the FIFRA preemption provision. *Id.* at 447. The Court explained, FIFRA "does not preclude States from imposing different or additional remedies, but only different or additional requirements." *Id.* at 448 (emphasis in original).

Notwithstanding the Georgia Court of Appeal's application of *Bates* to the Vaccine Act, this Court rejects that application. Simply because the *Bates* Court, when faced with two plausible alternative readings of the FIFRA preemption statute, opted for the reading that disfavors preemption, the *Ferrari* appeals court applied a similar reading to § 22(b). *Ferrari*, 2007 WL 1933129, at *4. However, Bates does not require a court to automatically accept a plausible interpretation of a statute which disfavors preemption. Even assuming, *arguendo*, that Plaintiffs have offered a plausible alternate reading of § 22(b), the *Ferrari* holding takes only one part of the *Bates* ruling out of its context, and gives it broader scope than is appropriate.

The *Ferrari* court agreed with *Sykes*, *Blackmon*, and *Militrano* that the legislative history of the Vaccine Act clearly demonstrates congressional intent to completely preempt design defect claims, and also considered the Bates rule disfavoring preemption as "outcome determinative," irrespective of congressional intent. *Ferrari*, 2007 WL 1933129, at *5. However, *Bates* itself relies on the congressional intent behind FIFRA when applying the rule. 544 U.S. at 449 ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption.") The Court continued, "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.*

Thus, even though there is a "basic presumption against pre-emption," *id.*, a court must look to whether that presumption accords with Congress' intent in enacting a specific law. The Third Circuit, discussing implied conflict preemption, very recently held, "[t]his question is basically one of congressional intent. Did Congress, in enacting the Federal Statute, intend to exercise its constitutionally delegated authority to set aside the laws of a State? If so, the Supremacy Clause requires courts to follow the federal, not state, law." *Pennsylvania Employees Benefits Trust Fund v. Zeneca, Inc.*, No. 05-5340, slip op. at 20 (3d Cir. Aug. 17, 2007) (*quoting Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996)).

Importantly, as previously noted, the *Bates* Court held FIFRA not to be "a comprehensive statute to justify an inference that Congress had occupied the field to the exclusion of the States." *Id.* at 441-42. In the case of FIFRA, the Supreme Court found the long history of tort litigation against pesticide manufacturers "emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." *Bates*, 544 U.S. at 450 (*citing Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 613 (1991)). As another court has recently noted, the *Bates* decision "was moored tightly to the specific preemption clause at issue." *Mills, M.D., v. Giant of Maryland, LLC,* 441 F. Supp. 2d 104, 107 (D.D.C. 2006) (dismissing as preempted claims against milk and milk-product marketers for failing to warn of the risks of lactose intolerance). "*Bates* merely underscores the need to pay close attention to the scope of the [federal statute's] preemption clause and assists the court in framing the questions to be addressed." *Id.* at 107. *Bates* does not decide the question whether the Vaccine Act preempts all design defect claims, or whether there must be a case-by-case determination as to whether a vaccine is unavoidably unsafe.

3. The Vaccine Act preempts design defect claims

This case does not materially deviate from the facts in the precedents cited above, as regards Plaintiffs' design defect claims. In all four vaccine

design defect cases cited above, the plaintiffs asserted that a vaccine was defectively designed because the defendants knew of the risk of adverse reactions. In all four cases, the plaintiffs posited a theoretical alternative design which would have resulted in a safer vaccine. Plaintiffs here make the same arguments.[10]

Comment k, by offering the example of the rabies vaccine, presents a situation in which a manufacturer should be immune from liability because administering the vaccine is always preferable to not administering it, despite the risks inherent in the vaccine. In this example, the individual has only two choices: the individual must either accept the risks associated with rabies, or the risks associated with its treatment. This dichotomy explicitly assumes that there is no better, alternative rabies vaccine which avoids the risk inherent in the first one. *See* Restatement (Second) of Torts § 402A cmt. k ("There are some products which, *in the present state of human knowledge*, are quite incapable of being made safe for their intended and ordinary use." (emphasis added)) Comment k, therefore, suggests that the question of whether a particular vaccine is unavoidably unsafe – and

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[10]Indeed, while the plaintiffs in *Blackmon*, *Ferrari*, and *Sykes* complained of the use of the mercury-based preservative, thimerosal, the *Militrano* plaintiffs advanced precisely the argument brought here; namely, that the defendant should have sought earlier approval for a safer alternative. *See Militrano*, 769 N.Y.S.2d at 847.

therefore subject to the immunity from suit posited by comment k – is a question of fact for a jury to determine. That is, the trier of fact must decide whether the challenged vaccine is the only design available, "in the present state of human knowledge."

Sykes' four conclusions, *supra* Part V.B.1, provide the standard by which this Court finds design defect preemption under the Vaccine Act. Using this framework, the following conclusions may be drawn: First, allowing case-by-case inquiries into whether a particular vaccine is unavoidably unsafe would do nothing to protect vaccine manufacturers from suit from design defects, since such an inquiry would require a finder of fact to consider the manufacturer's design against a purported safer alternative.

Second, the Vaccine Act provides for the NVICP to, "promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines." 42 U.S.C. § 300aa-27(a)(1). That the same program which provides no-fault remedies to injured vaccine recipients also promotes the discovery of safer alternative designs, suggests Congress intended to provide an umbrella under which manufacturers would improve the safety of their products while remaining immune from design defect claims made possible by the successful innovation of safer alternative designs.

Third, the Vaccine Court's no-fault compensation scheme reflects the other side of the balance Congress struck between the policy of widespread distribution of childhood vaccines and the need to compensate those injured effecting that policy. *See* H.R. Rep. No. 99-908 at 13; *supra* Part V.A.

Finally, whereas Sykes understands the Vaccine Act to "mirror[] this established area of tort law for unreasonably unsafe products," 484 F. Supp. 2d at 303, this Court concludes that § 22(b) is broader than comment k, so that the Vaccine Act preempts state law determinations of whether a vaccine is unavoidably unsafe, and therefore entitled to comment k immunity. In approving the design of a vaccine, the FDA considers the safety and efficacy of that vaccine. *See* 42 U.S.C. § 262(a) ("The Secretary [Health and Human Services] shall approve a biologics license application (i) on the basis of a demonstration that (I) the biological product that is the subject of the application is safe, pure, and potent."); *see also Blackmon,* 328 F. Supp. 2d at 665. An FDA-approved vaccine design includes the side-effects of that vaccine, and is therefore, by statutory definition, the unavoidably unsafe product subject to comment k immunity. As such, § 22(b) of the Vaccine Act represents part of a comprehensive statutory scheme which preempts all design defect claims brought under state tort law. Applying the "parallel requirements" holding of *Bates*, the Court concludes Congress did not intend to allow a case-by-case determination as to whether a vaccine

is unavoidably unsafe. Doing otherwise would allow state common law to impose additional requirements on vaccine manufacturers wishing to avoid liability, rather than merely providing additional remedies for violating federal law. *Compare Bates,* 544 U.S. at 448 ("[FIFRA] does not preclude States from imposing different or additional remedies, but only different or additional requirements.") *with* 42 U.S.C. § 300aa-22(b)(1) ("No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine related injury or death ... , if the injury or death resulted from side effects that were unavoidable .... ").

To further this point, the Court will address *Rohrbough v. Wyeth Laboratories, Inc.,* 719 F. Supp. 470 (D.W. Va. 1989), in which the court found that a vaccine manufacturer may only avail itself of comment k immunity after "first demonstrat[ing] that its vaccine was 'unavoidably unsafe,'" *id.* at 477, and upon which Plaintiffs rely for their argument against design defect preemption. The court reached its conclusion based on West Virginia's adoption of comment k. The court denied the defendant manufacturer's summary judgment motion because factual issues existed as to the question of unavoidability. What Plaintiffs fail to account for, however, is that *Rohrbough* does not implicate the Vaccine Act because the Vaccine Act was not operative. Although *Rohrbough* was decided three years after the passage of the Act, the facts of the case show that the vaccine in question was administered in 1983 and 1984, before Congress

enacted the Vaccine Act. *See id.* at 472. Section 22 of the Vaccine Act only applies to vaccines administered after October 1, 1988. 42 U.S.C. § 300aa-22(b)(1). As such, *Rohrbough* represents precisely the action against which § 22 is meant to protect vaccine manufacturers, not an argument in favor of Plaintiffs' design defect claims.

Counts I and III are claims for design defects preempted by the Vaccine Act, and will be dismissed with prejudice.[11]

c. Failure-to-Warn Claims

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[11]Plaintiffs' claim that they have exhausted their administrative remedies is beside the point. The Vaccine Act does not provide for district courts to sit in review of the Vaccine Court, as Plaintiffs argument would suggest. Indeed, Plaintiffs only allege state law violations in tort, and this Court has jurisdiction solely due to the diversity of the parties, and not because of a federal question. *See* This Court's Memorandum and Order dated March 27, 2006 (Doc. No. 13), 2007 WL 782437. The Vaccine Act grants exclusive jurisdiction over NVICP claims to the Vaccine Court. *See* 42 U.S.C. § 300aa-12(a). Appeals go to the Federal Circuit. 42 U.S.C. § 300aa-12(f). Only after the Vaccine Court has issued a ruling, or has failed to do so, does the Act allow claimants to take their case beyond the NVICP. However, civil actions in tort are manifestly different from proceedings before the Vaccine Court. As discussed, *supra* Part V.A., the Vaccine Court is a no-fault compensation scheme that requires no showing of negligence, or even of causation. H.R. Rep. No. 99-908 at 12. That standard is far different from the traditional tort claims which must be brought after a party rejects the findings of the Vaccine Court, alleging negligence or strict liability, as are discussed below.

The Vaccine Act clearly bars failure-to-warn claims based on a failure to directly warn the injured party or the injured party's legal representatives. 42 U.S.C. § 300aa-22(c). The Amended Complaint, however, alleges Defendant withheld specific information from doctors about particularly dangerous batches of the vaccine, including Hannah Bruesewitz' own doctor. (Am. Compl. ¶ 35.) As the court found in *Blackmon*, allegations of a failure to warn "doctors and medical intermediaries" are not subject to the prohibition of § 22(c). 328 F. Supp. 2d at 666. Even so, the Vaccine Act also grants a vaccine manufacturer the presumption of a proper warning if the manufacturer "shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act." 42 U.S.C. § 300aa-22(b)(2). "The Vaccine Act imposes a burden of production on the manufacturer to show material compliance with FDA regulations." *Blackmon*, 328 F. Supp. 2d at 667.

Once the manufacturer meets that burden, however, the burden shifts to the plaintiff to present evidence that the manufacturer engaged in fraud or wrongful withholding of information from the Secretary of Health and Human Services either during or after the approval process, or by "clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with [the laws and regulations regarding drug approval proceedings]." *See* 42 U.S.C. §§ 300aa-22(b)(2)(A) and (B).

Defendant first argues that Plaintiffs' failure-to-warn claim merely repackages their design defect claims under a different title. The Court rejects Defendant's interpretation of Plaintiffs' failure-to-warn claim because Plaintiffs have alleged facts which fit squarely into the two exceptions to the failure-to-warn immunity provided in § 22(b)(2). The issues on summary judgment therefore become whether Wyeth has made a showing of evidence to avail itself of the presumption of proper warnings, and if so whether Plaintiffs can mount facts sufficient to rebut the presumption.

1. Defendant are entitled to the presumption of proper warning

Defendant relies on the Declaration of Dennis J. Foley, Ph.D., and the exhibits attached thereto to demonstrate that throughout its history of use, from 1943 until it was taken from the market in 1998, TRI-IMMUNOL® has been licensed by the appropriate federal agency. Moreover, the FDA approved the package insert containing the warning provided along with the vaccine administered to Hannah Bruesewitz. Most importantly, Plaintiffs do not dispute that the warning provided by Defendant complied with the relevant federal laws and regulations. Defendant is therefore entitled to the presumption that TRI-IMMUNOL® was "accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(2).

2. Plaintiffs have failed to rebut the

presumption

The Amended Complaint does not allege fraud or wrongful withholding of information from the Secretary of Health and Human Services. Plaintiffs have omitted that allegation in the original Complaint in filing the Amended Complaint. In any case, Fed. R. Civ. P. 9(b) requires Plaintiffs plead fraud with particularity rather than supplying a mere "recitation of the Vaccine Act language." *Sykes*, 484 F. Supp. 2d at 306. Plaintiffs must therefore show, "by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with [the laws and regulations regarding drug approval proceedings]." 42 U.S.C. §§ 300aa-22(b)(2)(B). In support of their failure-to-warn claim, Plaintiffs only cite the affidavit of Donald H. Marks, M.D., Ph.D., and the exhibits attached thereto. Plaintiffs have identified which lot produced the dose of TRI-IMMUNOL® administered to Hannah Bruesewitz, as well as the Vaccine Adverse Event Reporting System ("VAERS")[12] report confirming deaths and other adverse events associated with that lot. (Marks Aff.

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[12]VAERS is a database created, pursuant to the Vaccine Act, by the FDA and the Centers for Disease Control and Prevention to receive reports about adverse events which may be associated with vaccines. "The primary purpose for maintain the database is to serve as an early warning system for adverse events not detected curing pre-market testing." (Marks Aff. Ex. 14., "Important Information from the FDA about the Vaccine Adverse Event Reporting System".)

Ex. 15.) Plaintiffs also offer the deposition testimony of Hannah Bruesewitz' doctor, Jane M. Breck, M.D. to establish that, had she known the vaccine to be administered to Hannah had come from a lot associated with at least two deaths and more than 30 injuries, she would not have administered that particular dose of vaccine.[13]

According to Dr. Marks, such a batch, associated with deaths and adverse reactions, is sometimes referred to as a "Hot lot." Dr. Marks relies on a memorandum from the Department of Health and Human Services to define a "Hot lot" as a "fill lot[] that exceeded a threshold of $\geq$ 2 deaths or $\geq$ 2 convulsions or $\geq$ 10 total reports." (Marks Aff. Ex. 8.) The memorandum, however, actually refers to such a lot as a "potential hot fill lot[]" and goes on to explain that the total number of doses distributed must be known in order to account for a potential reporting bias. (*Id.*)(emphasis added). In other words, according to the evidence produced by the Plaintiffs themselves, a "Hot lot" is not defined by the total number of adverse incidents, but rather by the rate at which those incidents occurred. Plaintiffs have produced no evidence from which a trier of fact could infer that the dose in question originated in a lot of vaccine associated with a disproportionate number of adverse health effects. Indeed, Plaintiffs provide evidence that Wyeth and its relevant

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[13]These two documents, the VAERS report, and the deposition of Dr. Breck, substantiate paragraphs 4-6 of Plaintiffs' Further Statement of Undisputed Facts.

corporate predecessors were aware that certain lots of TRI-IMMUNOL® were associated with higher rates of adverse events, and that Wyeth took steps to withdraw those lots from distribution. (Marks Aff. ¶¶ 6-7 Ex. 2, 3.) Therefore, Plaintiffs have failed to establish that the dose of vaccine administered to Hannah Bruesewitz originated in a "Hot lot."

Under Pennsylvania law, whether warning labels on prescription drugs are adequate is a matter for the jury to decide. *Incollingo v. Ewing,* 444 Pa. 263, 289-90 (1971) ("We think that whether or not the warnings on the cartons, labels and literature of [the defendant drug manufacturer] in use in the relevant years were adequate, and whether or not the printed words of warning were in effect cancelled out and rendered meaningless ... , were questions properly for the jury.") In the instant case, however, Congress has established a presumption of adequate warning to which this Court has found Wyeth is entitled. Plaintiffs have not pointed to any evidence showing the lot from which Hannah Bruesewitz' dose came was a "Hot lot" or that Wyeth acted in a way to suggest it believed it was a "Hot lot." There has been no showing by Plaintiffs that the vaccine dose in question was materially different from any other vaccine dose for which the warning had been approved. Plaintiffs simply have no evidence to support their contention that Hannah Bruesewitz received a dose of vaccine originating from a "Hot lot." Therefore, Plaintiffs have failed to present "clear and convincing" evidence that Defendant failed to exercise due care. The Court will grant

summary judgment in favor of Defendant as to Count II of the Amended Complaint.

D. Manufacturing Defect

Defective manufacture provides a cause of action for strict liability in Pennsylvania. *See Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 748 (B.D. Pa. 2007) (Robreno, J.) (*citing Phillips v. A-Best Prods. Co.*, 542 Pa. 124 (1995)). Under Pennsylvania law, a plaintiff alleging a product manufacturing defect based on a theory of strict liability must show that (1) the product was defective; (2) the defect was the proximate cause of the plaintiffs injuries; and (3) the defect causing the injury existed when the product left the seller's hand. *Id.* at 749 (*citing Pavlik v. Lane Limited/Tobacco Exporters Int'l*, 135 F.3d 876, 881 (3d Cir. 1998). "A product will be deemed defective only if it 'left the supplier's control lacking any element necessary to make it safe for its intended use or possessing any feature that renders it unsafe for the intended use.'" *Commonwealth Dept. of General Services v. U.S. Mineral Products Co.*, 2007 WL 1892076, * 5 (Pa. Cmmw. Ct. July 3, 2007) (*quoting Azzarello v. Black Bros. Co., Inc.*, 480 Pa. 547, 559 (1978)).

Wyeth concedes the Vaccine Act does not preempt claims for manufacturing defects. Instead, Wyeth argues Plaintiffs' manufacturing defect claim must fail because there is no dispute that the dose administered to Hannah Bruesewitz was made

within design specifications, and therefore was not defective.[14] Plaintiffs first counter that they allege a classic manufacturing defect claim, asserting that the dose administered to Hannah Bruesewitz had "an inappropriate balance between neuro-toxins and endo-toxins in the pertussis vaccine." (Am. Compl. ¶ 39.) Setting aside the legal consequences if such a claim were true (which Wyeth disputes), Plaintiffs have offered absolutely no evidence to support this allegation, as is their burden to do in response to Defendant's summary judgment motion. Meanwhile, Wyeth provides the Declaration by Mary B. Ritchey, Ph.D., in which she states, "The pertussis bacterium does not contain a recognized 'neuro-toxin' component. Indeed, I do not understand what part of the pertussis vaccine plaintiffs refer to when they allege that 'neuro-toxins' were not balanced with endotoxins in TRI-IMMUNOL® .... To my knowledge it has never been proven that whole-cell pertussis vaccine has a neuro-toxic effect." (Ritchey Decl. ¶ 9.) Defendant has therefore offered evidence that the specific manufacturing defect alleged by Plaintiffs, an imbalance of "neuro-toxins" and "endotoxins," did not exist. Plaintiffs have offered no evidence

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[14]As with Plaintiffs' failure-to-warn claim, Wyeth first characterizes the allegations in Count IV as merely another iteration of the original design defect claim. The Court rejects this argument because Plaintiffs clearly allege that the vaccine administered to Hannah Bruesewitz differed materially from the intended design in that the lot from which that dose originated was allegedly more prone to adverse reactions that intended by the design. (*See* Am. Compl. ¶ 37.)

sufficient to raise a genuine issue as to this fact.

Even without direct evidence of a manufacturing defect, one may be inferred where there is circumstantial evidence of a malfunction. To that end, Plaintiffs hold up the phenomenon of the "Hot lot" as circumstantial evidence of a manufacturing defect. Under Pennsylvania law, Plaintiffs' argument is known as the "malfunction theory."

> The malfunction theory permits a plaintiff to prove a defect in a product with evidence ofthe occurrence of a malfunction and with evidence eliminating abnormal use or reasonable, secondary causes for the malfunction. The plaintiff is relieved from demonstrating precisely the defect yet it permits the trier-of-fact to infer one existed from evidence of the malfunction, of the absence of abnormal use and of the absence of reasonable secondary causes.

Barnish v. KWI Bldg. Co., 916 A.2d 642,646 (Pa. Super. Ct. 2007).

Pennsylvania precedent is devoid of cases applying the malfunction theory to the allegedly defective manufacture of vaccines or other prescription medical products. The general rule, however, is "[t]he questions when and where a defect

originated should be left to the finder of fact so long as reasonable and well balanced minds (could) be satisfied from the evidence adduced that the defective condition existed when the [product] was delivered." *Id.* (*quoting Kuisis v. Baldwin-Lima-Hamliton Corp.*, 457 Pa. 321 (1974)). Plaintiffs offer evidence that when a "Hot lot" is discovered, the manufacturer changes the batch rather than producing more lots of vaccine from that batch. (Marks Aff. ¶¶ 6, 7 Ex. 2, 3.) If the production process for a DPT vaccine includes the removal from production of batches which are less safe than intended, an inference must be made in favor of Plaintiffs at the summary judgment stage that any such batches are defectively manufactured. *See Barnish*, 916 A.2d at 647.

However, the first prong of a manufacturing defect claim still requires the plaintiff to prove the product was defective. "Even though 'proof of a specific defect is not essential to establish liability under [the malfunction] theory, the plaintiff cannot depend upon conjecture or guesswork." *Barnish*, 916 A.2d at 646 (*quoting Woodin v. J.C. Penny Co., Inc.*, 629 A.2d 974, 976 (Pa. Super. Ct. 1993)). As discussed above, *supra* Part V.C., Plaintiffs have failed to offer evidence that the lot from which Hannah Bruesewitz' dose of vaccine derived was a "Hot lot." As such, they have raised no genuine issue of material fact for trial as to whether the vaccine was defective, even under the malfunction theory.

Moreover, even if Plaintiffs had established

that the vaccine was defective in this case, Plaintiffs have absolutely no evidence to satisfy the second prong of the test to determine liability for a manufacturing defect. That is, Plaintiffs cannot show "the defect was the proximate cause of the plaintiffs injuries." *Soufflas*, 474 F. Supp. 2d at 749. In *Barnish*, from which the definition of the malfunction theory is quoted, the defendant did not dispute that the alleged manufacturing defect was the proximate cause of the plaintiffs' injuries. 916 A.2d at 644. In the instant case, Wyeth specifically denies the DPT vaccine caused any injury to Hannah Bruesewitz. Plaintiffs' only evidence there was anything wrong with the particular vaccine lot from which Hannah Bruesewitz' dose came is the VAERS report for that lot number. (*See* Marks Aff. ¶ 24 Ex. 15.) However, Plaintiffs have no evidence to support the proposition that the specific lot caused any of those adverse reactions, let alone the specific reaction suffered by Hannah Bruesewitz. Indeed, Plaintiffs' own evidence negates the possibility that one may draw an inference from a VAERS report that the vaccine caused the reaction:

> The report of an adverse event to VAERS is not a documentation that a vaccine caused the event. ... Some infants will by coincidence experience such an event shortly after a vaccination. In such situations, the event may be caused by an infection, congenital abnormality, injury, or some other provocation. Because of such

> coincidences, it is usually not possible to be sure whether a particular adverse even resulted from a concurrent condition or from vaccination, even when it occurred soon afterward. Therefore, doctors and other vaccine providers are encouraged to report adverse events, whether or not they believe that the vaccination was the cause. Since it is difficult to distinguish a coincidental event from one truly caused by a vaccine, the VAERS database will contain events of both types.

("Important VAERS Information" Marks Aff. Ex. 14.)

Accordingly, in the absence of any evidence that the dose of Defendant's vaccine administered to Hannah Bruesewitz was defective, or that it was the proximate cause of Plaintiffs injuries, summary judgment will be granted in favor of Defendant as to Count IV.[15]

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[15]Wyeth alternatively argues that Pennsylvania state law does not allow for a finding of strict liability for design defect or manufacturing defects in this case. Plaintiffs counter that the Vaccine Act preempts any bar to their claim. Pennsylvania has adopted Section 402A of the Restatement (Second) of Torts. *Mazur v. Merck & Co.,* 964 F.2d 1348 (3d Cir. 1992). Therefore, Pennsylvania also provides immunity to the manufacturers of prescription drugs pursuant to comment k. *See Hahn v. Richter,* 673 A.2d 888, 891 (1996) ("the manufacturer's negligence, is the only recognized basis of liability,") However, not only does the

VI. Conclusion

Counts I and III allege design defects, and are therefore preempted by the Vaccine Act. Counts II and IV are not preempted; however, Plaintiff has failed to produce evidence raising issues of material fact. Accordingly, Defendant's Motions for Summary Judgment will be granted as to all Counts. An appropriate Order follows.

Vaccine Act preempt state law allowing claims arising out of defectively designed vaccines, it also explicitly prohibits states from "establish[ing] or enforc[ing] a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle." 42 U.S.C. § 300aa-22(e). The Vaccine Act clearly permits manufacturing defect claims under § 22(b)(1), without reference to the theory of liability. Therefore, strict liability claims for manufacturing defect are not barred by the Vaccine Act. As such, the preemption provision in § 22(e) applies, and Pennsylvania's bar to strict liability claims for manufacturing defects, enunciated in Hahn, is preempted. As the Court will grant summary judgment as to Count III based on Vaccine Act preemption and Count IV on the merits, preemption of the *Hahn* rule does not impact the outcome of this case.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

BRUESEWITZ, et al.,
Plaintiffs,

v.

Civil Action
NO. 05-5994

WYETH, INC.,
Defendant.

[DATE STAMP
ILLEGIBLE]

ORDER

AND NOW, this __ day of August 2007, upon consideration of Defendant's Motions for Summary Judgment, and all the Responses and Replies thereto, it is hereby ORDERED that Defendant's Motions to for Summary Judgment (Docs. No. 22, 73, 88) are GRANTED. Judgment is entered in favor of Defendant and against Plaintiffs. The Clerk shall close this case.

BY THE COURT:

/s/
Michael M. Baylson, U.S.D.J.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 07-3794

RUSSELL BRUESEWITZ; ROBALEE BRUESEWITZ, parents and natural guardians of Hannah Bruewewitz, a minor child and in their own right,

Appellants

v.

WYETH INC.
f/k/a
WYETH LABORATORIES,
WYETH-AYERST LABORATORIES,
WYETH LEDERLE,
WYETH LEDERLE VACCINES,
AND LEDERLE LABORATORIES

SUR PETITION FOR REHEARING

Present: SCIRICA, *Chief Judge*, SLOVITER, McKEE, RENDELL, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, and WEIS, *Circuit Judges**

The petition for rehearing filed by appellants

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*The vote of the Honorable Joseph F. Weis, Jr., Senior Circuit Judge of the United States Court of Appeals for the Third Circuit, is limited to panel rehearing.

in the above-entitled case having been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

BY THE COURT,

/s/ D. Brooks Smith
Circuit Judge

Dated: May 6, 2009
MB/cc: Collyn A. Peddie, Esq.
Lauren Elliot, Esq.
Richard W. Mark, Esq.
Henry F. Reichner, Esq.
Michael T. Scott, Esq.
Daniell Thomasch, Esq.

CONSTITUTION OF THE UNITED STATES OF AMERICA

ARTICLE VI. MISCELLANEOUS PROVISIONS

Art. VI, Cl. 2

Cl. 2. Supreme law.

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY
COMPENSATION PROGRAM
ADDITIONAL REMEDIES

42 USCS § 300aa-22

§ 300aa-22. Standards of responsibility

(a) General rule. Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings.

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988] if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [*21 USCS §§ 301* et seq.] and *section*

351 of the Public Health Service Act [*42 USCS § 262*] (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows–

> (A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2) [*42 USCS § 300aa-23(d)(2)(A) or (B)*], or
>
> (B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings. No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988] solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction. The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a

vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption. No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle [*42 USCS §§ 300aa-10* et seq.].

[LETTERHEAD DEPARTMENT OF JUSTICE
OFFICE OF CONSUMER LITIGATION]

December 11, 2006

Hon. Michael M. Baylson
United States District Judge
Eastern District of Pennsylvania
3810 U.S. Courthouse
Sixth and Market Streets
Philadelphia, PA 19106-1768
Via hand delivery

RE: Bruesewitz v. Wyeth, Inc.,
No. 05-CV-5994-MMB (E.D. Pa.)

Dear Judge Baylson:

I write in response to your letter dated November 9, 2006, addressed to Eric Blumberg of the Food and Drug Administration's (FDA's) Office of Chief Counsel and to Sharon Swingle of the Justice Department's Civil Division Appellate Staff, in which Your Honor requested that FDA and/or the U.S. Department of Health and Human Services (HHS) prepare and submit an *amicus* brief on the issues presented by the defendant's motion for summary judgment in the above-captioned case.

After careful review, HHS and FDA have determined that they do not have views on the issues presented by the defendant's motion for summary judgment and thus are unable to provide assistance

to the court in the form of an *amicus* brief in this matter. This case concerns 42 U.S.C. 300aa-22(b), a provision of the Vaccine Act. As you know, that provision protects vaccine manufacturers from civil liability from certain claims, but only to the extent that the vaccine "was properly prepared and was accompanied by proper directions and warnings." 41 U.S.C. 300aa-22(b)(1). The statute further states, *inter alia*, that for purposes of this provision, "a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all of the requirements under the Federal Food, Drug, and Cosmetic Act [FDCA] ..., applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought." *Id.* § 300a-22(b)(2).

Certain vaccine injury claims may directly implicate the scope of the FDCA and the FDA's implementing regulations. For example, there may be a substantial issue as to whether a manufacturer has complied with the FDCA and the FDA's implementing regulations. Here, however, based on their review of the papers filed in this case, HHS and FDA understand that the primary issue before this Court is the extent to which "design defect" claims are foreclosed by 42 U.S.C. 300aa-22(b).

Although. the Secretary of HHS administers the National Vaccine Injury Compensation Program (NVICP), the particular provision of the Vaccine Act at issue here comes into play only after a party has

exhausted his or her remedy under the NVICP either by rejecting his or her NVICP judgment under section 300aa-21(a) or by withdrawing his or her petition under section 300aa-21(b) if a decision or judgment is not issued within the specified time period. When a party properly completes his or her proceeding in the NVICP and then files a civil action for damages such as the present case, the Secretary is not a party to that civil action and does not administer the provisions, such as section 300aa-22(b), that govern such civil actions.

HHS and FDA appreciate the Court's courtesy in providing them with an opportunity to submit an *amicus* brief in this case and regret that they are unable to assist the Court by providing views on the issues presented.

Sincerely yours,

Eugene M. Thirolf
Director
Office of Consumer Litigation

cc: Counsel for plaintiff:
James J. Byrne, Esq.
McNichol, Byrne. & Matlawski, PC
606 E Baltimore Pike
Media, PA 19063
Fax: 610-565-9531
Via e-mail to: Jjbyrne@mbmlawoffice.com

Jim Hart, Esq.

Thao Ho, Esq.
Williams Bailey Law Firm LLP
8441 Gulf Freeway, Suite 600
Houston, TX 77017
Via fax to: 713-643-6226

John R. Fabry, Esq.
Jones and Granger
10000 Memorial Drive
Suite 888, PO Box 4340
Houston, TX 77210-4340
Via fax to: 713-956-7139

Robert E.J. Curran, Esq.
Curran & Byrne PC
PO Box 30
Media, PA 19030
Via e-mail to: Lawoffice@curranandbyrne.com

Counsel for defendant:

Daniel J. Thomasch, Esq.
Holly Mitchell Dellenbaugh, Esq.
Lauren Elliot, Esq.
Orrick Herrington & Sutcliffe LLP
666 Fifth Ave.
New York, NY 10103
Via e-mail to: dthomasch@orrick.com, hdellenbaugh@orrick.com, lelliot@orrick.com

Reetu Dandora, Esq.
Reed Smith LLP
2500 One Liberty Place

1650 Market St.
Philadelphia, PA 19103
Via e-mail to: Rdandora@reedsmith.com

Counsel for government:

Eric Blumberg, Esq.
Office of the General Counsel
Food and Drug Division
U.S. Dept. of Health & Human Services
5600 Fishers Lane, Room 615
Rockville, MD 20857

Virginia A Gibson, Local Counsel
Assistant U.S. Attorney
Chief, Civil Division, E.D. Pa.

[LETTERHEAD OF U.S. DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA]

November 9, 2006

Sharon Swingle, Esquire
Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave., N.W.
Room 7250
Washington, DC 20530

Eric Blumberg, Esquire
Office of the General Counsel
Health & Human Services
5600 Fishers Lane, Room 615
Rockville, MD 20857

Re: Bruesewitz, et al. v. Wyeth
C.A. No. 05-5994

Dear Ms. Swingle and Mr. Blumberg:

I request that the United States, specifically the Food & Drug Administration and/or the Department of Health & Human Services, submit an amicus brief on the issues presented by the defendant's pending Motion for Summary Judgment in this case, which seeks damages for injuries sustained as a result of ingestion of a vaccine, which Motion would require me to interpret the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300AA-1 et seq., regulations issued by the Food &

Drug Administration.

For your information, I am enclosing a copy of the briefs filed by the parties. However, I have not copied the attachments to the defendant's brief which are generally copies of legal decisions or other legal documents.

Please advise how quickly you can file your *amicus brief* in this case, hopefully within thirty days or less.

By copy of this letter to counsel in the case, I am authorizing them to submit additional materials directly to you for your consideration.

Very truly yours,

/s/

Michael M. Baylson

MMB:lm
enclosures

cc Virginia Mason, Esquire, AUSA, James Byrne, Esquire, Robert Curran, Jim Hart, Thao Ho, Daniel Thomasch, Holly Dellenbaugh, Lauren Elliot, Reetu Dandora

OPPOSITION BRIEF

Supreme Court, U.S.
FILED
OCT 7 - 2009
OFFICE OF THE CLERK

No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ,
Parents and Natural Guardians of HANNAH BRUESEWITZ,
a Minor Child and In Their Own Right,

Petitioners,

v.

WYETH, INC. f/k/a WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES and LEDERLE LABORATORIES,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF IN RESPONSE TO PETITION FOR A WRIT OF CERTIORARI

Daniel J. Thomasch
Counsel of Record
Richard W. Mark
E. Joshua Rosenkranz
John L. Ewald
ORRICK, HERRINGTON
& SUTCLIFFE LLP
666 Fifth Avenue
New York, New York 10103
212-506-5000

Counsel for Respondents

QUESTION PRESENTED

In the 1980s, the costs and risks of product liability litigation drove several vaccine manufacturers out of the market, causing shortages of vaccines essential to public health programs. Congress averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986. The Act shielded vaccine manufacturers from categories of tort litigation, directed federal agencies to develop safer childhood vaccines, and established a Vaccine Court to administer a no-fault remedy for vaccine-related injuries. The Act's express preemption provision states that "[n]o vaccine manufacturer shall be liable in a civil action" if the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Does the Vaccine Act expressly preempt a state-law claim against a vaccine manufacturer based on an allegation that the vaccine-related injury could have been avoided by a vaccine design allegedly safer than the one approved by the U.S. Food and Drug Administration for use nationwide?

RULE 29.6 STATEMENT

Respondent Wyeth, Inc., improperly identified in the caption as Respondents "Wyeth, Inc. f/k/a Wyeth Laboratories, Wyeth-Ayerst Laboratories, Wyeth Lederle, Wyeth Lederle Vaccines and Lederle Laboratories," states that Wyeth is a publicly traded corporation. No publicly held corporation owns 10% or more of its outstanding shares.

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INTRODUCTION

Respondents ("Wyeth") agree with Petitioners ("plaintiffs") that the Court should grant certiorari in this case to resolve a crucial public health issue upon which the lower courts are split. Twenty-five years ago, a deluge of cases asserting claims just like this one drove vaccine manufacturers from the market and threatened the nation's supply of childhood vaccines. Congress stabilized the market by enacting the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* (the "Vaccine Act" or "Act"), which created a new, no-fault compensation program for vaccine-related injuries and included an express preemption provision (Section 22) that limits the scope of damage claims that can be advanced against vaccine manufacturers. The question presented by the petition is whether Section 22 categorically preempts all design defect claims, which were central to the 1980s litigation crisis.

In answering that question in the affirmative, the United States Court of Appeals for the Third Circuit expressly—and correctly—rejected the conclusion of the Georgia Supreme Court in *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).[1] The Georgia Supreme Court held that

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[1] The vaccine manufacturer defendants in *Ferrari* petitioned for a writ of certiorari, which petition is pending. No. 08-1120. This Court called for the views of the United States on the petition, *American Home Products Corp. v. Ferrari*, 129 S. Ct. 2786 (2009), but the Solicitor General has not yet filed her brief in response to the invitation.

Section 22 does not preclude design defect claims unless the manufacturer demonstrates, case by case, that there was no safer design that could have avoided the injury.

The Court should not wait for another case to take up the question of which interpretation of Section 22 is correct. The stability of the nation's childhood vaccine supply remains precarious. Determining which state law claims Section 22 allows against vaccine manufacturers will affect the development and supply of vaccines. If the conflicting interpretations of the Georgia Supreme Court and the Third Circuit are left unresolved, vaccine manufacturers will face the potentially devastating prospect of thousands of lawsuits challenging the design of their FDA-approved vaccines in courts across the country. Approximately 5,000 petitions—all premised on the claim that a child's autism was caused by vaccines—are pending in the federal no-fault vaccine compensation program ("Vaccine Court"). Regardless of how the Vaccine Court decides those petitions, every claimant has the potential to reject the judgment and elect to file a civil action for damages.

Apart from the need to review the question presented, however, Wyeth disagrees with almost everything else in plaintiffs' petition. Plaintiffs inject implied preemption issues into their petition; but those issues have no relevance to the question presented here of express preemption under the Vaccine Act. Wyeth also disagrees with plaintiffs that the Third Circuit erred in its ultimate result. The Third Circuit—joining every court to address

the issue outside Georgia—correctly decided that the Vaccine Act categorically preempts all design defect claims. The court properly rejected plaintiffs' construction of the statute—which would permit unfettered litigation against vaccine manufacturers—as antithetical to Congress's primary aim of ensuring a stable supply of childhood vaccines.

Because a litigation deluge would threaten the supply of childhood vaccines, the Court should grant certiorari in this case and verify which interpretation of the express preemption provision is correct, the Third Circuit's or the Georgia Supreme Court's.

STATEMENT OF THE CASE

In 1986, Congress Saw That Vaccine Litigation Threatened To Cause A Public Health Crisis

The petition's discussion of the Vaccine Act is incomplete. Plaintiffs write as if Congress intended for the Vaccine Act to compensate allegedly vaccine-injured individuals and nothing more. But the Vaccine Act's new approach to compensation for vaccine-related injuries is only one part of a multi-faceted public health program Congress created.

Congress recognized in 1986 that "[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. No. 99-908, at 4 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. For example, pertussis (or whooping cough) is a serious, highly communicable respiratory disease.

In 1934, there were 265,269 reported cases of pertussis and 7,518 deaths. *See* Staff of Subcomm. on Health and the Environment, 99th Cong., *Childhood Immunizations* 9-10 (Sept. 1986) ("Subcomm. Rep."). After 40 years of widespread use of the whole-cell pertussis vaccine, the incidence of pertussis dropped to 2,276 reported cases in 1984 and only 12 deaths. *Id.* Congress enacted the Vaccine Act when the burden of vaccine litigation costs threatened to undermine the spectacular public health gains brought about by nationwide vaccination.

In the 1980s, vaccine manufacturers faced a proliferation of product liability claims involving childhood vaccines. Most of these cases were like this one, involving claims that the diphtheria, tetanus, and pertussis ("DTP") vaccine was defectively designed because there was an unlicensed, allegedly safer, alternative vaccine in existence that would have prevented the same diseases. The result of that litigation explosion, according to Congress, was a vaccine market so "unstable and unpredictable" as to threaten the supply of vaccines necessary to carry out childhood immunization programs. *See* 1986 U.S.C.C.A.N. at 6346. Observing that litigation had already driven manufacturers from the market, Congress concluded that the "withdrawal of even a single [additional] manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." *Id.* at 6348. Congress addressed the public health crisis with the Vaccine Act.

Policy Components Of The Vaccine Act

The objective of universal vaccination to combat infectious disease and promote the common public health requires a stable supply of safe and effective vaccines. Through the Vaccine Act, Congress sought: (1) to keep vaccine manufacturers in the market; (2) to provide fair compensation to the few who suffer adverse side effects from vaccination; and (3) to have improved vaccines developed. The key to achieving these goals was to create a comprehensive, national vaccine policy—from developing safer vaccines, to a new paradigm for providing compensation and litigating injury claims.

Keeping vaccine manufacturers in the market. The element of the statutory scheme that protects vaccine manufacturers from the sort of burdensome litigation that Congress found had driven manufacturers out of the market is Section 22(b)(1). It provides, in full:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1). Neither party interprets Section 22 to preclude any and all state tort claims. The parties agree that the Vaccine Act permits claims against a manufacturer for injuries caused by a vaccine not manufactured according to its FDA-

approved formula (i.e., not "properly prepared") or not accompanied by proper directions and warnings for use. The question presented by the petition is whether Section 22 leaves open the possibility of other claims for damages, specifically design defect claims, which were central to the litigation in the 1980s.

Before filing a civil action, a person seeking damages for a vaccine-related injury must file a petition for compensation in the Vaccine Court, which is an adjunct to the Court of Federal Claims. 42 U.S.C. §§ 300aa-11(a)(2), 12(c), 21(a). Compensation claims are decided on a no-fault basis. *Id.* §§ 300aa-13, 14, 15(i). A Vaccine Court claimant does not need to prove that the injury could have been avoided through a safer design or that the vaccine was otherwise defective—as tort law would require—but only that there is a causal link between the administered vaccine and the injury. *See id.* § 300aa-13. After receiving a judgment in Vaccine Court, the claimant can either accept the judgment or reject it and file a civil action, subject to several substantive and procedural constraints. *See* 42 U.S.C. § 300aa-21.

The National Vaccine Program. The Vaccine Act established a National Vaccine Program ("NVP") to promote the development of improved, safer vaccines for use in immunization programs nationwide. 42 U.S.C. § 300aa-27(a)(1). Through this program, nearly a dozen federal agencies, including the Food and Drug Administration ("FDA"), work together "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention

against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. Congress established a "[m]andate for safer childhood vaccines" and assigned the Secretary of the Department of Health & Human Services ("HHS") with the responsibility to "assure improvements in . . . licensing, manufacturing, processing, testing, labeling, warning, . . . and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." 42 U.S.C. § 300aa-27(a)(1), (2).

The Vaccine Act left in place the laws and regulations that make the FDA responsible for regulating the formulation, production, and labeling of childhood vaccines, which are biological products subject to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Public Health Service Act, 42 U.S.C. § 262. Such oversight is done through the FDA's Center for Biologics Evaluation and Research ("CBER"), which was created in 1988, the same year the Vaccine Act became effective. CBER is entirely distinct from those aspects of the FDA that regulate drugs and devices. Following FDA licensure, a manufacturer cannot change the vaccine formula or the labeling without FDA approval. *See* 21 C.F.R. §§ 601.2, 601.12.

DTP Vaccine

Wyeth disputes almost all of the factual assertions in plaintiffs' Statement of the Case. Those assertions that purport to have citational support largely do not cite to the record below, but rather to statements made in decisions from completely unrelated cases. There is no need to

catalog all of those inaccuracies here because they are not relevant to the pure question of law presented by the petition. But Wyeth will address the most misleading of the statements about the regulatory history of the DTP vaccine at issue and purported safer alternative vaccines.[2]

The pertussis component in TRI-IMMUNOL®, the DTP vaccine at issue, consists of a suspension of whole, killed pertussis cells.[3] A. 1035a, ¶ 6; 866a, ¶ 6. Plaintiffs argue that Wyeth should have marketed a "safer alternative vaccine[ ]," i.e., an entirely different vaccine to prevent the same diseases that TRI-IMMUNOL® addresses. Pet. at 3. Plaintiffs contend that the "safer alternative vaccine[ ]" was either: (1) an acellular pertussis vaccine, which contained selected components of the

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[2] Wyeth denies that the DTP vaccine caused the minor plaintiff's injuries, a position which is consistent with the views of numerous medical organizations and agencies that have rejected plaintiffs' causation theory. *See, e.g.*, American Academy of Pediatrics, Committee on Infectious Diseases, *The Relationship Between Pertussis Vaccine and Central Nervous System Sequelae: Continuing Assessment*, 97 Pediatrics 279 (1996); Institute of Medicine, *DTP Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (1994). Causation, however, was not at issue in plaintiffs' appeal to the Third Circuit and is not before this Court on the petition.

[3] Citations to A. __ are to the Appendix filed below. Plaintiffs admitted a number of facts in the district court summary judgment briefing. In this section, when two citations to the Appendix follow a sentence, they refer respectively to the relevant paragraph in Wyeth's statements of undisputed fact and plaintiffs' response admitting that the paragraph is not disputed.

pertussis cell; or (2) the Tri-Solgen vaccine, which was a "fractionated cell" vaccine that contained part of the pertussis bacterium, but unlike acellular vaccines, was neither characterized (identifying the parts of the cell) nor purified (utilizing only specific parts of the cell).

Indisputably, at the time of the minor plaintiff's immunization in April 1992, the only DTP vaccines that were licensed for immunizing infants used a "whole cell" pertussis vaccine component. A. 1036a, ¶ 12; 867a, ¶ 12. The FDA did not license for infants a DTP vaccine containing an acellular pertussis component until mid-1996, more than four years after the immunization of the minor plaintiff. A. 1036a, ¶ 9; 867a, ¶ 9.

Nevertheless, plaintiffs argue that Wyeth should have marketed the Tri-Solgen vaccine (which was withdrawn in the 1970s by its manufacturer Eli Lilly) instead of the FDA-approved TRI-IMMUNOL® vaccine. The FDA, however, concluded that the Tri-Solgen design was inferior to that of TRI-IMMUNOL®. In 1982, Wyeth Laboratories sought approval to market a vaccine based on the Tri-Solgen design, but the FDA rejected the license application, expressing "the need for several design improvements." *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 753 (Ohio 1988).

Plaintiffs also argue that the FDA did not license an acellular vaccine for infants simply because Wyeth failed to seek FDA approval for such a vaccine. That is false. The delay in licensing the acellular vaccine for infants in the United States was the product of the FDA's appropriate insistence that

all such vaccines be proven through clinical trials to be as efficacious as the existing whole-cell vaccine. CDC, *Pertussis Vaccination: Acellular Pertussis Vaccine for Reinforcing and Booster Use*, 41 MMWR 1 (Feb. 7, 1992). That requirement took years to fulfill in the United States. A. 1036a, ¶ 9; 867a, ¶ 9. Japan did not have a similar requirement, and in the face of a pertussis epidemic in 1981, the Japanese government permitted acellular pertussis vaccines to go to market with no efficacy testing and only limited clinical studies of immunogenicity and safety. CDC, *Pertussis Vaccination: Acellular Pertussis Vaccine for Reinforcing and Booster Use*, 41(RR-1) MMWR 1 (Feb. 7, 1992). Indeed, having neither required nor received clinical trial data to show that acellular vaccines were efficacious, regulatory authorities in Japan limited administration of acellular pertussis vaccines to children with more developed immune systems, i.e., children two years of age and older. *Id.*

The Proceedings Below

On April 3, 1995, plaintiffs filed a Vaccine Court petition seeking compensation for injuries the minor plaintiff allegedly suffered as the result of a DTP vaccination administered in April 1992. After an evidentiary hearing, the Vaccine Court rendered a judgment dismissing plaintiffs' petition with prejudice for failing to establish that the DTP vaccine caused the minor plaintiff's injuries.[4]

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[4] Plaintiffs correctly assert that residual seizure disorder associated with DTP vaccine was removed from the Vaccine Injury Table in 1995, thus placing on plaintiffs the burden of

Bruesewitz v. Sec'y of HHS, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Dec. 20, 2002). Plaintiffs did not appeal that judgment to the Court of Federal Claims or the Federal Circuit; instead, they elected to reject the judgment of the Vaccine Court and to pursue civil litigation.

After Wyeth moved for summary judgment, the district court, *sua sponte*, invited the FDA and HHS to submit an amicus brief. A-112. Plaintiffs are simply wrong that HHS and FDA responded to the invitation by stating that in this case there was "no preemption of all design defect claims." Pet. at 13. Instead, the two agencies chose not to take a position on the preemptive scope of the Vaccine Act at that time. The FDA and HHS responded by letter to the district court that they did not then have an official view on the preemption issue because the agencies are not parties to civil actions commenced after a claimant has properly exhausted the administrative compensation process, and do not administer provisions that govern such civil actions. A-107-09.

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proof as to medical causation. What plaintiffs fail to mention, however, is that HHS removed residual seizure disorder from the Table because it determined there was no "*medical evidence* to support" the presumption. National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678, 7691 (Feb. 8, 1995) (emphasis added). Even with the condition removed from the Table, plaintiffs still were able to argue in Vaccine Court that the DTP vaccine in-fact caused the minor plaintiff's injuries. All of plaintiffs' causation theories were rejected by the special master. *Bruesewitz*, 2002 WL 31965744, at *12-*17.

After "extensive discovery," the district court granted summary judgment to Wyeth on plaintiffs' entire complaint. A-54-56. The district court held, *inter alia*, that Section 22(b)(1) of the Vaccine Act expressly preempted plaintiffs' design defect claims. A-87.

The Third Circuit affirmed the district court's judgment. The Third Circuit concluded that the statutory text, structure, and legislative history of Section 22 showed "a 'clear and manifest' expression of congressional intent" to preempt design defect claims. A-30. In so ruling, the Third Circuit considered and explicitly rejected the Georgia Supreme Court's analysis, stating that it did "not consider the *Ferrari* Court's reading [of Section 22] to be compelling." A-28. The court found that "[e]ach of the objectives [of the Vaccine Act] extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute," leading to the "very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act." A-36.

ARGUMENT

I. ON THE QUESTION PRESENTED, THE THIRD CIRCUIT'S DECISION DIRECTLY CONFLICTS WITH THE GEORGIA SUPREME COURT'S DECISION.

Wyeth agrees with plaintiffs that there is a clear and irreconcilable conflict between a state's highest court (the Georgia Supreme Court) and a federal court of appeals (the Third Circuit) on whether the Vaccine Act expressly preempts all design defect

claims. The Third Circuit's holding that the Vaccine Act expressly preempts all design defect claims is consistent with all others on the issue outside of Georgia. *See Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845-46 (Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (App. Div. 2006), *leave denied*, 857 N.E.2d 1137 (N.Y. 2006) (table); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 299-303 (E.D. Pa. 2007); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664-66 (S.D. Tex. 2004); *Wright v. Aventis Pasteur, Inc.*, No. 3861, 2008 WL 4144386 (Pa. Ct. Com. Pl. Aug. 27, 2008), No. 336 EDA 2008 (Pa. Super. Ct. *argued* June 9, 2009). These courts have concluded that the Vaccine Act expressly preempts all liability of vaccine manufacturers unless the claimed injury could have been avoided by proper preparation of the administered vaccine or by including proper directions and warnings with the administered vaccine.

The Georgia Supreme Court reached the opposite conclusion when it held that the Vaccine Act's preemption clause "clearly does not preempt all design defect claims against vaccine manufacturers," "but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular vaccine were unavoidable." *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 238, 242 (Ga. 2008).[5]

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[5] The uncertainty for vaccine manufacturers created by the split between the Georgia Supreme Court and the Third Circuit on the question presented is reason enough to grant review.

Wyeth also agrees with plaintiffs that the critical issue should not be left to percolate any further. Recent events in the *Ferrari* trial court only underscore the urgent need for this Court to review this question. The petition for a writ of certiorari in *Ferrari* (No. 08-1120) is still pending before this Court. On June 8, 2009, the Court called for the views of the United States on the petition. Before the Solicitor General filed her brief, the respondents (plaintiffs below) filed a voluntary notice of dismissal *without prejudice* in the trial court.

This nonprejudicial withdrawal (the *Ferrari* plaintiffs are free to refile their case at any time) does not eliminate the public health problem the *Ferrari* decision created. As the Georgia Supreme Court said: its decision is—and will remain—the law of Georgia "at least until the Supreme Court of the United States has spoken on the issue." *Ferrari*, 668 S.E.2d at 243. The vaccine manufacturer defendants petitioned this Court to review *Ferrari* because the Georgia Supreme Court's decision lays the foundation to renew the very litigation crisis and subsequent threat to the vaccine supply that

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The additional case law plaintiffs cite does nothing to illuminate the question. Not one of the more than 30 cases cited in pages 17-20 of the petition squarely addresses the question of whether Section 22 of the Vaccine Act expressly preempts all design defect claims. For example, many of those decisions address *implied* field and conflict preemption arguments arising *under the FDCA* concerning claims that arose *before* the effective date of the Vaccine Act, October 1, 1988. *See, e.g., Hurley v. Lederle Labs Div. Of Am. Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1989).

Congress sought to avert with the Vaccine Act. That threat is addressed in Point II, *infra*. It is also described in depth in the *Ferrari* petition, the reply brief, and in the amicus brief submitted in support of the *Ferrari* petitioners by the American Academy of Pediatrics and 10 other physician and public health organizations.

The *Ferrari* plaintiffs' strategic maneuvering does raise the issue as to whether *Ferrari*, although still a viable case for review, is now the best vehicle to address and resolve the question presented. Because the dismissal was without prejudice, the *Ferrari* plaintiffs can refile at any time, and a live controversy therefore remains. *See City of Erie v. Pap's A.M.*, 529 U.S. 277, 288 (2000). The *Ferrari* plaintiffs' nonprejudicial dismissal could be considered an attempt to "manipulate the Court's jurisdiction to insulate a favorable decision from review." *Id.* However, given the *Ferrari* plaintiffs' present intent not to litigate, Wyeth acknowledges that the Court may view this case as a more suitable vehicle to resolve the question identically presented here and in *Ferrari*. In that event, Wyeth requests that the Court hold the *Ferrari* petition pending the Court's granting of certiorari in, and the disposition of, this case.

II. WYETH AGREES THAT THE QUESTION PRESENTED IS ONE OF NATIONAL IMPORTANCE.

Wyeth agrees with plaintiffs that whether the Vaccine Act expressly preempts all design defect claims is a crucial question of national importance. The parties are in agreement that Congress enacted

the Vaccine Act to ensure that there would be a stable supply of safe and effective vaccines today and in the future. But the parties (or, looked at another way, the Third Circuit and the Georgia Supreme Court) are diametrically opposed as to what Section 22 means. Plaintiffs assert that litigation against vaccine manufacturers over design defect claims will lead to a stable vaccine supply and improved vaccines, and Congress wrote Section 22 to allow that. The Third Circuit rejected that argument. This sharp disagreement over how Congress intended to ensure the continued availability of essential childhood vaccines is precisely the type of issue that this Court should resolve now.

The threat to the vaccine supply. Plaintiffs' remarkable assertion that the Third Circuit's ruling precluding litigation over design defect claims somehow "disrupted a stable vaccine supply for all children" (Pet. at 4) defies common sense and is provided without any explanation or citation. To the contrary, the pre-Vaccine Act history of the childhood vaccine market demonstrates, and the relevant legislative history reflects, that Congress appreciated that litigation disrupts the vaccine market. That reality was a driving force for the passage of the Vaccine Act, the creation of a Vaccine Court, and the preemption of all but a narrow range of liability theories in post-Vaccine Court cases.

Between 1980 and 1985, 299 lawsuits were filed against vaccine manufacturers seeking damages for injuries alleged to be caused by vaccines. Subcomm. Rep. at 85; *see also* Geoffrey Evans, *Update on Vaccine Liability in the United States*, 42 Clinical Infectious Diseases S130, S134 (2006). Nearly two-

thirds of those lawsuits, like this case, claimed injury from an allegedly defective DTP vaccine. Subcomm. Rep. at 86. This onslaught of litigation led to a precarious vaccine supply and caused Congress to find that "the withdrawal of even a single manufacturer" could lead to vaccine shortages and the resurgence of preventable infectious diseases. 1986 U.S.C.C.A.N. at 6348.

The Vaccine Act—through the no-fault compensation program and the preemption of certain tort claims—fundamentally changed the litigation status quo. In just two decades, the compensation fund has awarded more than $1.8 billion to over 2,200 families and individuals. HHS, *HRSA Awards Contract to Study Adverse Events in Childhood Vaccines* (Oct. 23, 2008), http://archive.hrsa.gov/newsroom/releases/2008/vaccinestudy.htm. Additionally, litigation against manufacturers of DTP and other vaccines slowed dramatically after the law took effect in 1988. *See id.*; Evans, *supra*, at S134. The post-Vaccine Act litigation that has been filed to date has been less costly. No case governed by the Vaccine Act against a vaccine manufacturer has proceeded to trial in the two decades since the Vaccine Act became effective.

Today, a new litigation threat to the nation's vaccine supply exists. Approximately 5,000 petitions are currently pending in the "Omnibus Autism Proceeding" in Vaccine Court. HRSA, *National Vaccine Injury Compensation Program Statistics Report* (Sep. 14, 2009, http://www.hrsa.gov/vaccinecompensation/statistics_report.htm. While the omnibus proceeding will decide for all of the pending cases whether there is a causal link between

childhood vaccines and autism, that ruling will have no preclusive effect outside of Vaccine Court. 42 U.S.C. § 300aa-23(e). Each claimant may elect to file a civil action after proceeding through Vaccine Court. Over 350 civil actions have been filed against vaccine manufacturers in various courts with allegations that childhood vaccines caused the recipient to develop autism.

The potential deluge of post-Vaccine Court litigation could lead to the same dangerous situation that existed in the mid-1980s. The number of childhood vaccine manufacturers has not increased since the enactment of the Vaccine Act. In the United States market today, as in 1986, there is still just one manufacturer for the polio vaccine, one for MMR, and two for the DTP vaccine. *Compare* 1986 U.S.C.C.A.N. at 6348, *with* FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/CBER/vaccine/thimerosal.htm (last updated Aug. 31, 2009). Thus, what Congress said in 1986 is true today: "The loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard." 1986 U.S.C.C.A.N. at 6348.

Plaintiffs and their amici argue that the Vaccine Act permits individuals who have exhausted the Vaccine Court remedy to elect to file civil actions asserting all the same sorts of claims that could have been asserted before the Act changed national policy. Indeed, plaintiffs argue that the Vaccine Act made it *easier* to sue vaccine manufacturers by *requiring* all states to allow design defect claims against manufacturers even if the state's common law does not recognize the theory. *See* Pet. at 36-37. Plaintiffs' amici postulate that the finished Vaccine

Act was a "compromise" (Amicus Br. at 4), but under their and plaintiffs' interpretation of the Act, this "compromise" resulted in a new no-fault compensation scheme, but no change at all to the rules governing civil actions or lessening of litigation risks that vaccine manufacturers faced.

Plaintiffs' view of the Vaccine Act flies in the face of Congress's clearly expressed intent. Congress erected two barriers to reduce lawsuits and thus keep manufacturers in the market: (1) it created a no-fault compensation system; and (2) it preempted all tort claims except manufacturing defect claims and certain failure-to-warn claims. Plaintiffs' interpretation of Section 22 renders both barriers essentially meaningless. Without the categorical preemption of vaccine design claims as intended by Congress, Vaccine Court could be reduced to just a checkpoint plaintiffs pass through on their way to civil court. Making it easier for plaintiffs to sue vaccine manufacturers would do nothing to ensure a stable vaccine supply because it would not lessen the litigation burden on vaccine manufacturers. That is not what Congress intended.

Regardless of Congress's intent with the Vaccine Act, amici argue that a civil remedy for design defect claims should be available because the "vaccine court has failed." Amicus Br. at 15. The premise of amici's argument is erroneous; Vaccine Court has not failed. The entire amicus brief, and much of plaintiffs', rests on the assumption that most, if not all, vaccine-related injury claims are valid. In fact, many of the claims asserted by claimants lack any

scientific basis whatsoever and thus denial of recovery in those actions is not a sign of failure.[6]

The vaccine/autism allegations at issue in the Omnibus Autism Proceeding are a case in point. Every government public health agency and reputable scientific body to address the question—including the FDA—has rejected allegations that childhood vaccines cause autism. *See, e.g.*, FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/cber/vaccine/thimerosal.htm. (last updated Aug. 31, 2009) (stating that FDA "conducted a comprehensive review of the use of thimerosal in childhood vaccines," and concluding that there was "no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions").

The most notable of the scientific reviews was the report of a panel of world-renowned experts appointed by the National Academy of Science's Institute of Medicine, which decisively declared that "**the evidence favors rejection of a causal relationship between thimerosal containing vaccines and autism.**" Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* 7 (2004) (emphasis in original).

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[6] Even if one assumed that amici's criticisms of the Vaccine Act are valid (which they are not), that the no-fault compensation program has failed in the eyes of certain parents is not a reason to ignore the language of the statute or the intent of the Congress that passed it.

In February, the Vaccine Court issued opinions in three test cases considering claimants' theory that the Measles-Mump-Rubella ("MMR") vaccine, in combination with thimerosal-containing vaccines, could cause autism. In each case, the Special Master found that the claimant had utterly failed to prove causation. All three of those decisions by the Special Masters were recently affirmed by the Court of Federal Claims.[7] Decisions by the Special Masters are soon expected on the three test cases considering claimants' theory that thimerosal-containing vaccines *alone* cause autism.

While the allegations in the Omnibus Autism Proceeding represent the current litigation threat to vaccine manufacturers, there is little reason to doubt that vaccines will continue to be blamed for a host of unrelated conditions. As the FDA has stated, vaccines are commonly accused of causing a wide variety of illnesses that happen to manifest themselves in early childhood at the time when children are also receiving vaccines. FDA, *VAERS Overview*, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/Overview/default.htm (last updated July 10, 2009). For example, one of plaintiffs' amici,

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[7] *See Cedillo v. Sec'y of HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *sustained*, No. 98-916V, 2009 WL 2998429 (Fed. Cl. Aug. 6, 2009); *Hazlehurst v. Sec'y of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), *sustained*, No. 03-654V, 2009 WL 2371336 (Fed. Cl. July 24, 2009); *Snyder v. Sec'y of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *sustained*, No. 01-162V, 2009 WL 2517755 (Fed. Cl. Aug. 11, 2009).

SafeMinds, has blamed essentially every major component of vaccines for causing autism, including "aluminum adjuvant, mercury preservative, endotoxins, and viral or bacterial antigens." SafeMinds, *Vaccines and Autism*, http://www.safeminds.org/mercury/vaccines-and-autism.html (last visited Oct. 7, 2009). It is a short step from such allegations to design defect litigation claims.

As long as vaccines are on the market, they will be blamed for one disease or another, regardless of whether those claims have any scientific merit. By preempting design claims, Congress intended to prevent meritless claims from ever being filed against manufacturers. But plaintiffs' Section 22 interpretation provides no such disincentive. It leaves the courthouse door wide open for approximately 5,000 claimants who—if plaintiffs' amici is to be believed—think they have a better chance for recovery before a jury than the Vaccine Court special masters. Amicus Br. at 13. The stakes for public health are high, and the Court should not leave the Vaccine Act preemption question for another day.

The threat to vaccine development. Plaintiffs also contend that the Third Circuit's interpretation of Section 22 destroys the manufacturers' incentive to create new and improved vaccines. Pet. at 28. This too is incorrect and was not the determination made by Congress in 1986.

In passing the Act, Congress recognized the need to spur the development of new vaccines and the improvement of existing ones. Congress determined that the development and evaluation of new and

improved vaccines to protect the population as a whole required a comprehensive and collaborative program among scientists in public health agencies, industry, and academic institutions. *See* 1986 U.S.C.C.A.N. at 6352. But Congress recognized that the high costs of, and potential liability from, product liability litigation involving existing vaccines threatened the development of new vaccines. 1986 U.S.C.C.A.N. at 6345; Subcomm. Rep. at 72. Thus Congress limited the tort claims that could be brought against manufacturers by enacting Section 22.

The scope of the protection afforded to vaccine manufacturers by Section 22 relates directly to the policy decisions Congress made in creating the National Vaccine Program. To the extent that state tort law traditionally provides an incentive for manufacturers to develop safer products, Congress addressed that policy goal by establishing a National Vaccine Program to research and develop improved, safer vaccines. For example, Section 27 of the Act mandates that HHS "promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines." 42 U.S.C. § 300aa-27(a)(1). There is no comparable program for prescription drugs or medical devices. For vaccines, product improvement and reevaluation to reduce risk and improve safety is not left solely to the marketplace and the self-interest of the private sector; nor is it to be indirectly prompted by the threat of jury verdicts over allegedly "unsafe" vaccine designs. Under the National Vaccine

Program, safer vaccines are to be actively pursued in the public interest, and the limited exceptions to Section 22(b)'s preemptive scope do not provide any "after-the-fact" evaluation role to juries.

Freed from the crush of product liability litigation, vaccine manufacturers, in conjunction with the various expert federal agencies, have had great success in developing new and improved vaccines. Since 1986, the collaboration has yielded seven new vaccines now on the routine childhood immunization schedule: hepatitis B; varicella; pneumococcal disease; influenza; hepatitis A; meningococcal disease; and rotavirus. *Compare* CDC, *Recommendation of the Immunization Practices Advisory Committee New Recommended Schedule for Active Immunization of Normal Infants and Children*, 35 MMWR 577 (Sep. 19, 1986), *with* CDC, *Recommended Immunization Schedules for Persons Aged 0-18 Years—United States, 2008*, 57 MMWR Q1 (Jan. 11, 2008).

For vaccine manufacturers, the combination of substantial protection from tort liability and government collaboration has led to recent successes outside of the Vaccine Act context. The H1N1 vaccine is a prime example. Multiple public health agencies, working with the manufacturers, have collaborated to design a new vaccine in record time to protect the population against the novel influenza A (H1N1) (commonly referred to as "swine flu") pandemic. *CDC, Questions & Answers—2009 H1N1 Influenza Vaccine*, http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm (last updated Oct. 5, 2009).

Pursuant to the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148 (2006), Kathleen Sebelius, Secretary of HHS, granted nearly complete legal immunity to the manufacturers of the H1N1 vaccines. Pandemic Influenza Vaccines—Amendment, 74 Fed. Reg. 30294-01 (June 25, 2009); 42 U.S.C. § 247d-6d. The PREP Act does provide one very limited exception to immunity if the "death or serious physical injury [was] proximately caused by willful misconduct" by a company or person covered by the Act. 42 U.S.C. § 247d-6d(d). Contrary to plaintiffs' argument that immunity from design defect claims would "destroy incentives" to make new and improved vaccines, the H1N1 vaccine experience demonstrates that limiting tort liability can result in unprecedented vaccine development.

Plaintiffs also argue that the PREP Act supports their interpretation of Section 22 because "[t]here would have been no need to make vaccines already covered by the Act subject to such legislation if Congress had already created an exclusive remedy for vaccine-related injuries." Pet. at 23. This argument fails for at least two reasons.

First, there is no overlap between the vaccines subject to the PREP Act and those covered by the Vaccine Act. Section 22 applies only to vaccines covered by the Act, which are those vaccines recommended for routine administration to children. *See* 42 U.S.C. §§ 300aa-14(e), 22(b), 33(5). The H1N1 vaccine and the other vaccines covered by the

PREP Act[8] are those that the Secretary of HHS has deemed necessary to respond to public health emergencies; these vaccines are not for routine administration to children.

Second, the PREP Act grants nearly complete legal immunity to manufacturers of the H1N1 vaccine. By contrast, the Vaccine Act strikes a careful balance between the compensation of vaccine-injured persons and the limitation of claims that can be brought against vaccine manufacturers in a civil action. Individuals alleging injury from a vaccine covered by the Vaccine Act could seek compensation if the injury was caused by a manufacturing defect or inadequate warnings, but as to vaccines covered by the PREP Act, no such claims may be asserted. The PREP Act therefore demonstrates that Congress felt it necessary to provide vaccine manufacturers with even greater protections from tort liability than is provided in the Vaccine Act.[9]

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[8] The countermeasures currently covered by declarations issued by the Secretary of HHS are: H1N1, H5N1, H2, H6, H7, and H9 pandemic influenza vaccines; anthrax; botulism; smallpox, and acute radiation syndrome. *See* HRSA, *Countermeasures Injury Compensation Program—Covered Countermeasures*, http://www.hrsa.gov/countermeasurescomp/countermeasures.htm. (last visited Oct. 7, 2009).

[9] Subsection (h) of section 247d-6d states that nothing in the section "shall be construed to affect the National Vaccine Injury Compensation Program under title XIX of this chapter." 42 U.S.C. § 247d-6d(h). This rule of construction demonstrates that Congress was aware of the Vaccine Act when it enacted PREP and that it intended for the different programs to occupy two distinct regimes.

III. THE THIRD CIRCUIT CORRECTLY FOUND THAT THE VACCINE ACT EXPRESSLY PREEMPTS ALL DESIGN DEFECT CLAIMS.

The Third Circuit correctly held that Section 22(b) of the Vaccine Act categorically preempts all design defect claims. While plaintiffs agree that this was the Third Circuit's holding (Pet. at 15-16), they contend that the court "relied heavily upon the 'complete' or field preemption principles." Pet. at 18. The Third Circuit did no such thing. The court relied on the text of Section 22, the legislative history of the Act, and the structure of the Vaccine Act to reach its decision that the statute expressly preempts design defect claims. A-42. What plaintiffs actually are criticizing is the court's use of the Vaccine Act's structure to support its interpretation of Section 22's text. That use is a common and accepted statutory interpretation technique when construing an express preemption provision. *See Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71 (2006) (relying on the structure, the purpose, and the legislative history of the federal statute to support the conclusion that the statute expressly preempts state law).

The Third Circuit, consistent with this Court's precedent, properly began its analysis with the presumption against preemption.[10] A-15-16. The

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[10] The petition's description of the presumption against preemption—an incomplete quotation from *Bates v. Dow Agrosciences LLC*—is inaccurate. Pet. at 32. This Court has

court found that the presumption was overcome because Congress clearly intended to preempt all design defect claims. A-42.

Citing to *Wyeth v. Levine*, plaintiffs contend that the case for preemption here is "'particularly weak [because] Congress had indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" Pet. at 32 (quoting *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009)). Plaintiffs' attempt to analogize this case to *Levine* is unavailing; the two cases present starkly different situations. The quoted excerpt from *Levine* was preceded by the statement that "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." *Id.* While Congress did not enact an express preemption provision for prescription drugs, it did, of course, enact one specifically for vaccines precisely because of the threat that state-law tort suits posed to the vaccine supply and, consequently, to public health.

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stated that it has a duty to accept a reading of a statute that disfavors preemption if that reading is equally or more plausible than the reading that favors preemption. *Bates*, 544 U.S. 431, 449 (2005). The Court has never ruled, however, that a merely plausible reading that results in no preemption must be followed over a more plausible reading that preempts state law.

The Language Of Section 22(b) Preempts Design Defect Claims. After addressing the presumption against preemption, the Third Circuit turned to the text of Section 22. Plaintiffs argue that the Third Circuit's interpretation omits the conditional phrase "'if the injury or death resulted from side effects that were unavoidable.'" Pet. at 29. This is incorrect. Reading the provision as a whole, the word "unavoidable" is modified by the 15 words that follow, so that vaccine manufacturers are immune from all civil liability except where the injury could have been avoided in either of two ways that Congress specified: (1) by proper preparation; *or* (2) by providing proper directions and warnings. There are no other exceptions to the broad scope of preemption in Section 22(b). Plaintiffs misread Section 22(b) as preemptive only where the alleged injury or death resulted from side effects that are proved to have been unavoidable *under any circumstances*. That construction simply reads out of the statute the words that follow "unavoidable."

Plaintiffs' reading also ignores how the phrase "the vaccine" is used after "unavoidable." The provision states that a manufacturer is not liable if the injury "resulted from side effects that were unavoidable even though *the vaccine* was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (emphasis added). Here, plaintiffs are alleging that the side effects could have been avoided if Wyeth marketed a "safer alternative vaccine[ ]" (Pet. at 3) that would have been designed to protect against the same diseases. However, allegations that a differently designed (purportedly safer) vaccine

would have avoided the plaintiff's injury are the type of claims that Congress intended to preempt. "[T]he vaccine" in Section 22 refers to the vaccine administered to the child, not a different vaccine that theoretically *could have been* designed, manufactured, tested, licensed, approved, and then given to the child.

In criticizing the Third Circuit's ruling, plaintiffs also assert that the absence of language in Section 22(b) explicitly identifying "design defect" claims supports their interpretation of the statute because Congress could have included such unequivocal language. Pet. at 31. Plaintiffs' criticism of statutory drafting misses the mark. Congress chose language to bar all claims—not just those explicitly labeled "design defect"—except for manufacturing defect and failure-to-warn claims.

In this respect, the Vaccine Act's preemption clause is unique among the express preemption provisions that this Court has examined in the past two decades in the context of common law tort claims. Unlike the provisions at issue in *Cipollone/Altria*, *Lohr/Riegel*, and *Bates*, which precluded general state law "requirements or prohibitions," the Vaccine Act's express preemption provision is aimed at tort claims. The sweeping terms of the provision—"no vaccine manufacturer shall be liable in a civil action for damages"—avoids the type of claim-by-claim preemption inquiry that was necessary in interpreting the preemption provisions in *Cipollone* or *Bates*. *See Bates*, 544 U.S. at 443-54; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 524-530 (1992). The language preempts *all*

claims, however pleaded, *except* for the two Congress specified. *See* 42 U.S.C. § 300aa-22(b).

The Authoritative Legislative History Reflects Congress's Intention To Bar Design Defect Claims. The Third Circuit also correctly found that the Committee Report on the bill supports the interpretation that the Vaccine Act preempts all design defect claims. The court found that the Committee Report "explicitly stated that injured individuals could only seek redress in the state tort system for certain manufacturing defect and warning claims." A-35-36. Specifically, the Committee Report explains:

> Given the existence of the compensation system in [the Vaccine Act], the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was *improperly prepared* or that it was *accompanied by improper directions or inadequate warnings* [they] *should pursue recompense in the compensation system, not the tort system.*

1986 U.S.C.C.A.N. at 6367 (emphasis added).

The Third Circuit properly rejected plaintiffs' reliance on "legislative history" from a subsequent Congress. Plaintiffs argue that a Committee Report that accompanied certain amendments made to the Vaccine Act in *1987* (relating to the funding of the

Act) constitutes evidence of Congress's intent in *1986*, when it adopted Section 22. That material is not entitled to consideration, much less reliance: it is not competent legislative history of the provision at issue in this case. *See Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)) ("subsequent legislative history is a 'hazardous basis for inferring the intent of an earlier' Congress"). The funding of the Act via the 1987 amendments did not concern in any way the Section 22 limitations on liability of vaccine manufacturers in civil actions and so do not provide any guidance on the intent behind the enacted law. The only modification the 1987 amendments made to Section 22 was to replace the words "effective date of this subpart" with "effective date of this part." Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330-221.

Plaintiffs contend that this Court's decision in *District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008), supports their argument that the post-enactment legislative statements should have been given weight by the Third Circuit. Pet. at 35. In fact, the decision demonstrates that the Third Circuit correctly rejected the post-enactment statements. In *Heller*, the Court distinguished between two types of statements. The Court found that "the examination of . . . sources to determine *the public understanding* of a legal text in the period after its enactment . . . is a critical tool of constitutional interpretation." *Id.* (emphasis in original). But the Court rejected precisely the type of post-enactment *legislative* statements plaintiffs rely on here. "'Postenactment legislative history,' a deprecatory contradiction in

terms, refers to statements of those who drafted or voted for the law that are made after its enactment and hence could have had no effect on the congressional vote." *Id.* That is exactly the case here. The statements made in 1987 could have had no effect on the Congress that enacted the language of Section 22 in 1986.

Plaintiffs' Construction Of Section 22 Is Contrary To The Structure Of The Vaccine Act. The Third Circuit was also correct in finding that the construction of Section 22 adopted by the Georgia Supreme Court was contrary to the structure of the Vaccine Act. As stated by the Third Circuit, the Georgia Supreme Court's construction "does not bar any design defect claims," but rather subjects all such claims to the evaluation of the court. A-29. In other words, plaintiffs' reading of Section 22(b) would not provide protection to a vaccine manufacturer unless and until the manufacturer made a showing at trial that no safer vaccine design was feasible. That would make Section 22(b) pointless. If read as plaintiffs propose, Section 22 would protect vaccine manufacturers only from a non-existent risk, because no state in 1986 imposed (or today imposes) design defect liability on vaccine manufacturers for injuries that could not have been avoided under any circumstances. Furthermore, vaccine manufacturers would only gain this "protection" in each case after incurring the substantial cost of litigating design defect claims to a jury verdict, which would be inconsistent with Congress's goal of reducing manufacturers' litigation costs.

Finally, the petition contends that Congress intended to create the "'awkward dichotomy'" that

plaintiffs' construction of Section 22 would entail. Pet. at 36 (quoting A-30). Some states, such as Pennsylvania and California, have concluded that strict liability is inapplicable to design defect claims involving prescription drugs. *See Hahn v. Richter*, 673 A.2d 888, 889-90 (Pa. 1996); *Brown v. Superior Ct.*, 751 P.2d 470 (Ca. 1988). The Third Circuit found that plaintiffs' construction would "create an awkward dichotomy" in such states by requiring courts to "engage in case-by-case analysis of all strict liability and negligent design defect claims brought under the Vaccine Act, while barring strict liability design defect claims against prescription drug manufacturers." A-30. There is certainly no evidence that Congress intended vaccine manufacturers to be subjected to *greater* litigation risk than drug manufacturers.

Plaintiffs attempt to counter this point by arguing that Congress has treated prescription drugs and medical devices differently by including an express preemption provision for medical devices, but not for prescription drugs. Pet. at 36. Plaintiffs' argument misses the Third Circuit's point. Congress wrote the Vaccine Act in response to a litigation crisis that threatened the supply of vaccines necessary to promote public health. The Vaccine Act overhauled the legal system and rules for compensating vaccine-related injuries with the intent, among others, to protect manufacturers from the type of litigation that had put them under such pressure in the 1980s. There was absolutely *no* intent on the part of Congress to open additional pathways for civil suits against vaccine

manufacturers, or to make such suits easier for plaintiffs to pursue.

CONCLUSION

The Court should grant the petition for a writ of certiorari in this case on the question as presented by Respondents and affirm the judgment of the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

Daniel J. Thomasch
Counsel of Record
Richard W. Mark
E. Joshua Rosenkranz
John L. Ewald
ORRICK, HERRINGTON & SUTCLIFFE LLP
666 Fifth Avenue
New York, NY 10103
212-506-5000

Counsel For Respondents

REPLY BRIEF

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In the Supreme Court of the United States

RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

REPLY TO OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

JOHN T. BOUNDAS
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway
Suite 600
Houston, Texas 77017-5051
(713) 230-2200

COLLYN A. PEDDIE
Counsel of Record
THE LAW OFFICES OF
COLLYN PEDDIE
440 Louisiana, Suite 1710
Houston, Texas 77002-1689
(713) 422-1205

Counsel for Petitioners

LEGAL PRINTERS LLC, Washington DC • 202-747-2400 • legalprinters.com

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 ["Vaccine Act" or "the Act"] expressly preempts certain design defect claims against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1); A-104.

The Question Presented is

Whether the Third Circuit erred in holding that, contrary to its plain text and the decisions of this Court and others, Section 22(b)(1) preempts all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not?

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INTRODUCTION

Respondent Wyeth[1] agrees with Petitioners that (1) a deep, mature, and irreconcilable conflict over the meaning and scope of Section 22(b)(1) exists between the Georgia Supreme Court's unanimous decision in *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008), and the Third Circuit's decision here; and (2) the proper interpretation of Section 22(b)(1) raises a question of exceptional national importance. As a result, Wyeth now joins Petitioners in asking this Court to grant *certiorari* in this case.

Although Wyeth concedes that this Court should grant *certiorari*, it seeks inappropriate revisions to the question presented. This Court must decide whether, using ordinary tools of statutory interpretation, Section 22(b)(1) should be construed to preempt ***all*** liability for design defects, even where the vaccine's side effects could have been avoided by a safer alternative design. Petitioners squarely ask that question. Wyeth would have this Court sidestep it.

Since the Bruesewitzes filed their petition, the *Ferrari* plaintiffs have voluntarily dismissed their claims and not refiled them.[2] Although this action

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[1]Curiously, Respondent Wyeth, Inc. disavows any connection to its former divisions and predecessors-in-interest, all of which are listed in the caption and collectively referred to as "Wyeth." *See, e.g.*, A-6, n.3 [opinion below] (naming Lederle Laboratories as Wyeth's predecessor-in-interest in producing the DTP vaccine at issue here).

[2]*See* Supplemental Brief for Respondents, *Am. Home Prods. Corp. v. Ferrari*, No. 08-1120, in the Supreme Court of the

arguably renders Wyeth's petition in *Ferrari* moot, it does not extinguish the conflict warranting *certiorari* here. In fact, it sharpens that conflict by effectively eliminating the possibility that the Georgia Supreme Court's decision could be deemed interlocutory. Thus, this case remains the appropriate vehicle to resolve these important national issues.

Finally, the Bruesewitzes dispute Wyeth's characterization of the facts. They take particular issue with Wyeth's attempt to suggest that there was no safer alternative to the vaccine administered to Hannah Bruesewitz. Wyeth made no such showing below. In fact, it intentionally avoided making such a showing in the trial court by claiming preemption,[3] and that issue is precisely what the trial court will decide if this Court remands this case.

Wyeth's depiction of events is not just incorrect; it starkly illustrates why this Court should grant *certiorari* here. The linchpin of Wyeth's preemption argument and the Third Circuit's decision is that forcing vaccine manufacturers to do exactly what Wyeth has done so gratuitously here would be so burdensome as to drive it and every other vaccine manufacturer from the vaccine market. Wyeth's actions prove otherwise.

United States ["*Ferrari* Supplemental Brief"], at 1a-2a (filed Oct. 7, 2009).

[3] *See Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 437 (E.D. Pa. 2007), *aff'd*, 561 F.3d 233 (3d Cir. 2009) (Wyeth contended that the existence of a safer alternative, Tri-Solgen, is irrelevant).

STATEMENT OF THE CASE

Petitioners dispute Wyeth's characterization of most of the contested facts here and, in particular, its attempt to show that there was no safer alternative vaccine.[4]

Although it criticizes Petitioners for allegedly doing so, Wyeth relies on an Ohio Supreme Court decision for proof that it could not have marketed Tri-Solgen, a split-cell DTP vaccine, and that Tri-Solgen was not safer than its vaccine was.[5] Wyeth's statements are incorrect and misleading. The FDA never determined that Tri-Solgen in its original formulation was unsafe or less safe than Wyeth's DTP vaccine. Instead, its subsequent problems related to Wyeth's proposed modifications to that design. *See, e.g., Ackley v. Wyeth Labs.*, 919 F.2d 397, 401 (6th Cir. 1990).

Wyeth also claims that Petitioners' causation theories have been rejected. That statement is also

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[4]Wyeth's criticism of the Bruesewitzes for their alleged failure to prove the existence of safer alternatives is misdirected and disingenuous. Wyeth bears the burden to prove its preemption affirmative defense by showing that its vaccine was "as safe as anyone could reasonably expect." H.R. REP. 99-908, at 26 (1986), *reprinted in* 1986 U.S.C.C.A.N 6344, 6367. By claiming preemption, Wyeth prevented the trial court from permitting full discovery on the issue, hearing evidence; or deciding it. The Bruesewitzes' sole purpose in outlining alternatives was to assure this Court that a bona fide dispute over the question of safer design exists.

[5]*See* Wyeth's Response at 9; *White v. Wyeth Labs.*, 533 N.E.2d 748, 752 (Ohio 1988). The *White* court expressly limited its holding to the record in that case. *Id.* at 753.

untrue and misleading. In medical research, "attribution of causation is typically not made until a level of very near certainty – perhaps 95% probability – is achieved." *Liable v. Sec'y of Health & Human Servs.*, 2000 U.S. Claims LEXIS 209 *61 (Fed. Cl. Sept. 7, 2000). By contrast, "determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain."[6] Thus, courts in DTP cases have found that "the totality of the evidence – including the striking temporal connection between the vaccine and [plaintiff's] initial seizure, the testimony of treating physicians, and the biologic and scientific plausibility of [the expert's] theory of causation – are sufficient to meet the Vaccine Act's preponderant evidence standard." *Andreu v. Sec'y of Health & Human Servs*, 569 F.3d 1367, 1382 (Fed. Cir. 2009).

Wyeth is also incorrect when it declares that "following FDA licensure, a manufacturer cannot change the vaccine formula or the labeling without FDA approval." Wyeth's Response at 7. To the contrary, the regulations cited contain "changes being effected" provisions, virtually identical to those discussed in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), that allow manufacturers to make labeling changes without prior FDA approval, and certain production changes with 30-days' notice to the FDA. *See* 21 C.F.R. § 601.12(c),(f)(2). These regulations obligate Wyeth to monitor and improve the safety of its vaccines.

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[6] *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994); *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

Petitioners also dispute Wyeth's and the trial court's characterization of the discovery here as "extensive." It was not, particularly on the question of safer alternatives.

Finally, Petitioners deny that there is a vaccine litigation "crisis." While Wyeth may lament the number and quality of autism-related lawsuits, the solution is not to preempt all design defect claims. Moreover, the Bruesewitzes take exception to Wyeth's statement that "by preempting design claims, Congress intended to prevent meritless claims from ever being filed against manufacturers." Wyeth's Response at 22. The Vaccine Act was not a tort "reform" statute designed to curb frivolous lawsuits. Instead, it was intended to streamline compensation in meritorious ones. *See Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995). In fact, the Act was originally intended to err on the side of compensation even if the injury did not actually result from administration of a vaccine. *See* H.R. REP. 99-908, 1, 4, 6-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345, 6359.

REASONS FOR GRANTING THE PETITION

I. ALL PARTIES AGREE THAT AN IRRECONCILABLE CONFLICT EXISTS OVER THE MEANING AND SCOPE OF SECTION 22(b)(1), A RECURRING QUESTION OF NATIONAL IMPORTANCE

In its response, Wyeth "[a]grees with Petitioners . . . that the Court should grant *certiorari* in this case to resolve a crucial public health issue upon which the lower courts are split." Brief in Response to Petition for

Writ of *Certiorari* ["Wyeth's Response"] at 1. In particular, "Wyeth agrees with [Petitioners] that there is a clear and irreconcilable conflict between a state's highest court (the Georgia Supreme Court) and a federal court of appeals (the Third Circuit) on whether the Vaccine Act expressly preempts all design defect claims." *Id.* at 12.

Wyeth also "[a]grees with [Petitioners] that the critical issue should not be left to percolate any further." *Id.* While further percolation will not resolve or advance the issues here, the persistence of a conflict creates intolerable and potentially unconstitutional unfairness to litigants in different jurisdictions. *See* Pet. at 24-25. Until that conflict is resolved, a family's address will largely determine whether or not it has the right to sue for vaccine-related injuries. *Id.* at 24.

Wyeth "[a]grees with [Petitioners] that whether the Vaccine Act expressly preempts all design defect claims is a crucial question of national importance." Wyeth's Response at 15. Despite this critical agreement, the parties disagree as to what those important national issues are.

While both parties agree that the conflicting rulings here disrupt a stable vaccine supply and thus threaten public health, they differ over how that disruption would occur. The Bruesewitzes recognize that "[t]he [Vaccine] Act modifies, but does not eliminate, the traditional tort system, which . . . provide[s] important incentives for the safe manufacture and distribution of

vaccines."[7] Congress retained those incentives by conditioning preemption of design defect claims on a showing that a vaccine's side effects were unavoidable,[8] a showing other drug manufacturers make routinely in the majority of states that embrace a case-by-case approach to RESTATEMENT (SECOND) OF TORTS § 402A, comment k (1965).[9] Preemption of all design defect claims, even where safer alternatives exist, would destroy those incentives to develop safer vaccines.

By contrast, Wyeth contends that, unless vaccine manufacturers alone are freed from the burden to show that their vaccines are "as safe as anyone could reasonably expect," H.R. REP. 99-908, at 26, the alleged litigation "crisis" of 1986 will reoccur despite the considerable protections the Act already affords and they will flee what is today a highly lucrative market.[10]

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[7] *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.); *see* H.R. REP. 100-391(I), at 691 (1987), *reprinted in* U.S.C.C.A.N. 2313-1, 2313-365; A-36.

[8] Wyeth's suggestion that President Reagan signed a law replacing existing incentives for private innovation with government-mandated vaccine development is fiction. *See* Wyeth's Response at 23-24; 42 U.S.C. § 300aa-27(a)(1), (2). The policy provision cited merely highlights the importance Congress attached to developing safer vaccines and suggests that Congress supported, rather than supplanted, the incentives for private vaccine innovation it expressly preserved in Section 22(b)(1). *See* H.R. REP. 100-391(I), at 691.

[9] *See, e.g., Ackley*, 919 F.2d at 400; *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000); Torburg, *Design Defect Liability and Prescription Drugs: Who's in Charge?*, 59 OHIO ST. L.J. 633, 639-41 (1998).

[10] Pfizer justified its recent $68 billion purchase of Wyeth, in part, on grounds that the acquisition would further Pfizer's goal

In fact, Wyeth later brags that the vaccine business is flourishing under those protections.[11]

This Court need not decide the merits, or lack thereof, of either of these arguments at this point. Both provide this Court with an issue of sufficient national importance to justify its granting *certiorari* here.

II. PETITIONERS' "QUESTION PRESENTED" CORRECTLY FRAMES THE ISSUES WARRANTING *CERTIORARI*. WYETH'S ALTERNATIVE DOES NOT

Although Wyeth agrees that this Court should grant *certiorari* on the meaning and scope of Section 22(b)(1), it attempts to rewrite the question presented. This Court should not utilize Wyeth's revisions.

The Bruesewitzes' question is clean and straightforward: whether, using ordinary tools of statutory interpretation,[12] Section 22(b)(1) should be

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to *enter* the global vaccine business by gaining rights to Prevnar, Wyeth's blockbuster children's pneumonia vaccine. *See, e.g.*, Pfizer 2008 Annual Review at 7, *available* at http://www.pfizer.com/investors/financial_reports/annual_reports/pfizer_wyeth.jsp.

[11] *See* Wyeth's Response at 24 (seven new childhood vaccines have been developed since 1986); *see also* Petition for Writ of *Certiorari*, *Am. Home Prods. Corp. v. Ferrari*, No. 08-1120, in the United States Supreme Court, at 22 (filed March 5, 2009) (Wyeth admits that "the post-Vaccine Act litigation that has been filed to date has been less costly").

[12] For example, this Court has recently reaffirmed that the "'task of statutory construction must in the first instance focus on the plain wording of the [express pre-emption] clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 556 (2008)

construed to preempt ***all*** liability for design defects, even where the vaccine's side effects could have been avoided by a safer alternative design. Pet. at i.

By contrast, Wyeth's "question presented" improperly focuses on a vaccine's FDA approval and thus repackages the same false choice Wyeth offered – and this Court rejected – in *Wyeth v. Levine:* whether a court, jury, or the FDA should decide if a vaccine is safe.[13]

FDA approval has never been considered tantamount to a finding that a vaccine's side effects will forever be unavoidable. Instead, "unavoidability" depends upon the ***relative*** safety of that vaccine's alternatives as they are developed. The FDA is not ordinarily called upon to make such a comparison.

Equally important, a court's determination that there were safer alternatives does not require it to make a companion finding that the FDA was wrong in approving the vaccine in the first place. There can, therefore, be no conflict between any judicial finding and any FDA determination that warrants preemption or the use of Wyeth's question in granting *certiorari.*

Instead, the issue here is whether, in passing the Act, ***Congress,*** not the FDA, decided that the side effects of all vaccines were unavoidable as a matter of law despite the conditional language it used in Section

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(quoting *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63 (2002)).

[13]*See* 129 S. Ct. at 1194; *see also* 21 U.S.C. §§ 331, 332, 334(a), (b) (misbranding is determined by jury).

22(b)(1).[14] Petitioners' "question presented" squarely addresses that issue.

Wyeth's question would also weigh an "allegation" that a vaccine-related injury could have been avoided by using a safer alternative against FDA approval. *See* Wyeth's Response at i. That is not the proper choice for the reasons discussed above and because it misallocates the burden of proof under the Vaccine Act and misapprehends the nature of preemption.

This Court has long held that preemption is an affirmative defense. *See, e.g., Caterpillar, Inc. v. Williams*, 482 U.S. 386, 392 (1987). All fourteen courts that have considered the issue, save the Third Circuit alone, have held that the Act provides a preemption affirmative defense, not an exclusive remedy. *See* Pet. at 17, n.9; 18, n.10 & cases cited therein. Moreover, when Congress wanted to create an exclusive remedy for a vaccine in the 1970s, it did so expressly.[15] Congress included no such language in the Act. This Court has held that such silence "is powerful evidence" that Congress did ***not*** intend to preempt. *Levine*, 129 S. Ct. at 1200.

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[14]The Committee Report it issued makes clear that "there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine . . ." H.R. REP. 100-391(I), at 691.

[15]*See, e.g.*, 42 U.S.C.§ 247b(k)(3) (1978) (repealed federal statute that provided: "The remedy against the United States . . . for personal injury or death arising out of the administration of the swine flu vaccine under the swine flu program shall be exclusive of any other civil action or proceeding for such personal injury or death . . .").

For these reasons, Wyeth has the burden to satisfy all prerequisites of its preemption affirmative defense. By implying otherwise, Wyeth misstates the issue to be decided here.

III. THE *FERRARI* DISMISSAL ONLY SHARPENS THE CONFLICT HERE AND DEMONSTRATES WHY THIS CASE IS THE APPROPRIATE VEHICLE FOR RESOLVING THESE IMPORTANT NATIONAL ISSUES

On September 21, the respondents in *Ferrari* informed this Court that they had voluntarily dismissed their state tort claims. . *See Ferrari* Supplemental Brief at 1. Because dismissal arguably divests this Court of jurisdiction over ***their*** claims, they ask the Court to dismiss Wyeth's petition for writ of *certiorari* as moot. *Id.* In its response in this case, Wyeth acknowledges these actions but argues that a live controversy still exists in *Ferrari* despite the dismissal[16] and that this Court should, therefore, hold the *Ferrari* case until this case is resolved.

No matter what this Court decides to do with the *Ferrari* petition, both Wyeth and the Bruesewitzes

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[16]Wyeth is probably incorrect. Wyeth has not alleged any ongoing injury, the linchpin of this Court's exception to the mootness doctrine in *City of Erie v. Pap's A.M.*, 529 U.S. 277, 288 (2000); *see also City News & Novelty, Inc. v. City of Waukesha*, 531 U.S. 278, 283-84 (2001). Second, in *Pap's A.M.*, the respondent simply voluntarily stopped the conduct complained of. In *Ferrari*, respondents formally dismissed their lawsuit and must refile to revive their claims. Finally, in *Pap's A.M.*, the mootness issue arose ***after*** *certiorari* was granted and the case had been fully briefed. This Court has not yet decided whether to take either case here and the Solicitor General has not yet filed her requested brief.

recognize that there remains an irreconcilable conflict warranting *certiorari* in this case. Wyeth admits that the Georgia Supreme Court's decision against it in *Ferrari* will remain the law of Georgia until this Court holds otherwise. *See* Wyeth's Response at 14; *Ferrari*, 668 S.E.2d at 243.

Equally important, the *Ferrari* dismissal effectively removes any concern that the Supreme Court of Georgia's ruling is interlocutory, an allegation the *Ferrari* respondents claim weakens the conflict here. *See* Brief in Opposition for Respondents, *Am. Home Prods. Corp. v. Ferrari*, No. 08-1120, in the Supreme Court of the United States, at 22-23 (filed May 8, 2009). As a result, the *Ferrari* dismissal only sharpens the conflict here and reinforces the need for this Court to grant *certiorari* in ***this*** case to resolve it.

CONCLUSION

For the reasons stated, this Court should grant the petition for writ of *certiorari*.

Respectfully submitted,

Collyn A. Peddie
Counsel of Record
THE LAW OFFICES OF
COLLYN PEDDIE
440 Louisiana, Suite 1710
Houston, Texas 77002-1689
Telephone: (713) 422-1205
Facsimile: (713) 844-3755

John T. Boundas
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway, Suite 600
Houston, Texas 77017-5051
Telephone: (713) 230-2200
Facsimile: (713) 643-6226

Counsel for Petitioners

AMICUS CURIAE BRIEF

No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ, *et al.*,

Petitioners,

v.

WYETH, INC., fka WYETH LABORATORIES, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF *AMICI CURIAE* NATIONAL VACCINE INFORMATION CENTER, ITS CO-FOUNDERS AND 24 OTHER ORGANIZATIONS IN SUPPORT OF PETITIONERS

MARY S. HOLLAND
245 Sullivan Street
New York, NY 10012
(212) 998-6212

ROBERT J. KRAKOW
Counsel of Record
1205 Franklin Avenue
Suite 110
Garden City, NY 11530
(516) 354-3300
rkrakow@me.com

Counsel for Amici Curiae
National Vaccine Information Center, its Co-Founders
and 24 Other Organizations

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 (Act) expressly preempts certain design defect claims against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1).

Did the Third Circuit err in holding that Section 22(b)(1) preempts all vaccine design defect claims, regardless of whether the vaccine's side effects are unavoidable?

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the parent advocates who helped draft the Act, §§ 300aa-1 *et seq*, and eleven organizations for children and families. They respectfully submit this brief in support of Petitioners. It is a matter of national importance that the judiciary interpret and apply the Act as Congress intended.[1]

Amicus curiae the National Vaccine Information Center (NVIC), founded in 1982 by parents whose children were injured or died following DPT vaccination, is widely recognized as the oldest, largest and most effective non-profit national organization advocating for the institution of vaccine safety and informed consent protections in U.S. public health programs. NVIC has assisted thousands of individuals who have suffered serious health problems, hospitalizations, injuries and deaths following vaccination. It promotes scientific research to evaluate vaccine safety and defends the ethical principle of informed

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[1] Pursuant to Sup. Ct. R. 37.2(a), *amici curiae* note that counsel of record for all parties received timely notice of NVIC's intention to file this brief. Pursuant to Sup. Ct. R. 37.6, *amici* note that no part of this brief was authored by counsel for any party. *Amici* also note that no party or counsel made a monetary contribution intended to fund the preparation or submission of this brief, and that no person or entity other than *amici* or their members made such a monetary contribution. This brief is filed with the consent of all parties.

consent for medical interventions, including vaccination, which carry a risk of injury or death.

Amici curiae Jeffrey Schwartz, Barbara Loe Fisher and Kathi Williams, former members of Dissatisfied Parents Together (DPT) and co-founders of NVIC, were the leading parent advocates in negotiating and drafting the Act. From 1973-79, Mr. Schwartz was Environmental Counsel for the House of Representatives Health and Environment Subcommittee of the Energy and Commerce Committee, the Subcommittee and Committee that drafted the Act. Ms. Fisher is President and Ms. Williams is Vice-President of NVIC.

Amicus curiae the New Jersey Coalition for Vaccine Choice advocates for the right to informed vaccination choices in the state of New Jersey.

Amici curiae the Elizabeth Birt Center for Autism Law and Advocacy (EBCALA), the National Autism Association (NAA), AutismOne, Autism United, U.S. Autism and Asperger Association (USAAA) and Talk About Curing Autism (TACA) are advocacy organizations for individuals and families affected by autism and other neurological disorders.

Amicus curiae SafeMinds (Sensible Action for Ending Mercury-Induced Neurological Disorders) is a nonprofit organization which investigates and raises awareness of the risks to infants and children of exposure to mercury from medical products, including thimerosal in vaccines.

Amicus curiae Parents Reviewing Education Plans (PREP) is an organization dedicated to assisting parents of students with individual education plans.

Amicus curiae the National Economic and Social Rights Initiative (NESRI) promotes a human rights vision for the United States that ensures dignity and access to the basic resources needed for human development and civic participation, including healthcare.

SUMMARY OF ARGUMENT

Hannah Bruesewitz was a healthy infant until she received a diphtheria, tetanus and pertussis (DPT) vaccine in 1995. Soon after vaccination, she suffered catastrophic injuries and now endures a lifelong residual seizure disorder. Her condition requires extraordinary care and financial resources. Hannah's family sought compensation under the Act but the compensation program denied her recovery. She then proceeded to trial court to argue that the DPT vaccine she received was defectively designed and that her injuries should have been avoided through use of a known, safer alternative. The court granted summary judgment against her, deciding that Section 22(b)(1) of the Act preempted all vaccine design defect claims. The Third Circuit affirmed the federal district court's decision to grant summary judgment. Fourteen years after Hannah's injury, she has yet to find justice.

The primary purpose of the Act is to compensate children. The Act created a compensation system as an alternative to the tort system, not a substitute.

Parents of vaccine-injured children stood up for their children's rights in drafting the Act and do so now in asking this Court to reverse the Third Circuit's decision to bar all design defect claims from civil court. The Act is a compromise that has created a compensation system and granted some liability protection to vaccine manufacturers. But that liability protection is not blanket immunity. Section 22 of the Act protects vaccine manufacturers from liability in a civil action "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."

The plain meaning and legislative history of the Act do not support preemption of all design defect claims. Indeed the parent *amici* who helped craft the Act would never have agreed to such preemption.

Unfortunately, the compensation program is not working as Congress intended. The program rejects most petitioners, as it did Hannah. Health and Human Services has failed to maintain and update the presumptions for injury that would allow the system to succeed. Given the compensation system's inadequacy, keeping the courthouse doors

open, as Congress intended, is more important than ever.

This Court's precedents, the Act's plain meaning and its legislative history support reversal of the Third Circuit's decision below.

REASONS FOR GRANTING THE WRIT

I. THE PURPOSE OF THE ACT IS TO COMPENSATE VACCINE-INJURED CHILDREN, NOT TO IMMUNIZE MANUFACTURERS FROM LIABILITY FOR ALL DESIGN DEFECTS.

The House Committee on Energy and Commerce (Committee), which drafted the Act in 1986, created the Vaccine Injury Compensation Program (Compensation Program or vaccine court) as an alternative to the tort litigation system, not its replacement. The tort system was neither compensating the children that vaccines injured nor ensuring a reliable vaccine supply. Tort litigation was costly, time consuming and usually undercompensated or failed to compensate victims. H.R. Rep. No. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347. The threats of onerous litigation to vaccine manufacturers and grossly insufficient compensation to the vaccine-injured risked the vaccine program itself. *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994) (citations omitted). *See also Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa.

2007). Congress created the Act to generously compensate vaccine victims, to ensure the vaccine supply and improve vaccine safety.

The legislators who drafted the Act understood that this carefully crafted scheme would fail without the support of parents whose children had already suffered vaccine injuries. As Barbara Loe Fisher recently explained:

> The young parents of vaccine injured children, who came to the table in the early 1980s at the request of congressional staff to fight for the rights of vaccine consumers and the vaccine injured, agreed to work on the Act because of promises made by Congress and the American Academy of Pediatrics (AAP) that the proposed legislation would provide a fair, expedited, non-adversarial, less traumatic, less expensive no-fault compensation alternative to civil litigation. We believed we were participating in the development of a law which would give – in the words of the then AAP Chairman – "simple justice to children."

Statement to the Advisory Commission on Childhood Vaccines (Nov. 18, 2008), (Fisher Statement) http://www.nvic.org/injury-compensation/vaccineinjury.aspx.

These parents, organized initially as Dissatisfied Parents Together (DPT), educated Congress and the public about vaccine injuries and the need for a no-fault compensation system. They worked for nearly five years, through multiple drafts and congressional hearings, to reach a workable compromise. At first, vaccine manufacturers and physician organizations advocated that an administrative no-fault system be victims' exclusive remedy. But parents insisted on the right to go to court after first filing in the compensation system if it was too slow, provided too little compensation or if victims wished to bring common law claims. The parents also insisted that the Act contain provisions to make vaccines safer, so that fewer children would be harmed in the future. *See generally,* Nitin Shah, *When Injury is Unavoidable: The Vaccine Act's Limited Preemption of Design Defect Claims*, Va. L. Rev. (forthcoming 2009), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1407343n; Division of Health Promotion and Disease Prevention, National Research Council, *Vaccine Supply and Innovation*, 183-92 (National Academies Press, 1985); Harris L. Coulter & Barbara L. Fisher, *A Shot in the Dark* 213-14 (Penguin Group, 1991); James Colgrove, *State of Immunity: The Politics of Vaccination in Twentieth-Century America*, 213-17 (University of California Press, 2006). As Dr. Martin H. Smith, AAP's past President wrote, "it became evident that working together with this group [DPT] was well advised and necessary." Martin H. Smith, *National Childhood Vaccine Injury Compensation Act*, 82 Pediatrics 264, 266 (1988).

After long, hard years of negotiation, Congress passed the Act in 1986. The Committee's report (1986 Report) accompanying the Act includes a section-by-section analysis of its provisions. Section 13 of the Act makes clear that the Compensation Program does not require petitioners to prove that the vaccine was defective or that the injury was avoidable. Rather, vaccine court would presume causation based on certain criteria, such as a temporal relationship between vaccination and symptoms specified in a "Vaccine Injury Table."

The Committee acknowledged the consequences of this presumption, intending to compensate even when the causal relationship was tenuous:

> The Committee...recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related ....[T]he Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

H.R. Rep. 99-908 at 8-35, *reprinted in* 1986 U.S.C.C.A.N. at 6349-76.

The Table's purpose was to ensure that the compensation process would remain administrative rather than litigious. If the Vaccine Injury Table contains a particular presumptive vaccine injury, the burden of proof shifts to respondent HHS to demonstrate that the injury was "unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B). For "off-table" injuries, a claimant must show that the vaccine more likely than not caused the injury. § 300aa-13. The Act also contemplates that the Secretary of HHS should add new vaccine injuries to the Table as new vaccines are mandated. H.R. Rep. 99-908, *reprinted in* 1986 U.S.C.C.A.N. at 6361.

Like in all compromises, no stakeholder in the negotiations got everything it wanted. Parents were forced to accept substantial limitations in the administrative system – mandatory filing, capped damages, no juries and limits on discovery. Manufacturers and physician groups were forced to accept that the administrative system would not be victims' exclusive remedy. And to get the deal done, Congress was forced to pass the Act without funding it. H.R. Rep. No. 100-391(I) (1987) *reprinted in* 1987 U.S.C.C.A.N. 2313-1. As AAP President Dr. Smith wrote in 1988 to his member pediatricians, "[t]his was the best compromise settlement...that could be reached." Smith at 268.

Several statements at the time the Act passed suggest that Congress recognized that victims, who had duly filed in the Compensation Program, could take design defect claims to court under Section 22(b). When presenting the Act to the full House of

Representatives for a vote, Rep. Henry Waxman, the Act's chief sponsor, stated that civil claims for "inadequately researched" vaccines would be preserved under Section 22. *National Childhood Vaccine Injury Act of 1986*, 99th Cong. Rec. 30760 (1986) (statement of Rep. Henry A. Waxman). *See also* Henry A. Waxman, *When a Vaccine Injures a Child: A No-Fault Way to Compensate*, Wash. Post, Oct. 9, 1986, at A27. Rep. Waxman's description of this claim, that a vaccine's design did not take adequate account of avoidable safety risks, would likely be a design defect. *See* Shah at 34.

Furthermore, the Committee explicitly rejected the opportunity to create a broad exemption for all design defect claims when it considered the Act. Proposals were considered by the Committee that would have explicitly preempted all design defect claims, but the final version did not contain those provisions. H.R. Rep. 100-391(I), at 691 (1987), *as reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365. By rejecting language that would have barred all design defect claims, Congress showed its intent to permit courts to decide on a case-by-case which side effects were genuinely "unavoidable." Moreover, the Committee emphasized in its 1987 Report when it authorized funding that it had not decided, as a matter of law, which, if any, vaccines were unavoidably unsafe: "This question is left to the *courts* to determine in accordance with applicable law." *Id.* (emphasis added).

The legislative history suggests that all the stakeholders – Congress, parents, manufacturers

and physicians – understood that victims preserved the right to take design defect claims to court. Respondent and its *amici* appear to be trying to achieve through the judiciary what they failed to obtain through Congress.

A. Congress Intended to Streamline Victims' Rights, Not Eliminate Them.

Parent advocates Schwartz, Fisher and Williams did not, and would not, have supported the Act if they thought that executive agencies or federal courts would later interpret it to foreclose access to a civil court remedy for design defect. They argued that because children face compulsory vaccination in order to attend school, their access to justice in the event of injury must be robust and must include design defect claims that manufacturers could have feasibly avoided.

They pointed to past court cases of vaccine design defects to demonstrate the need to preserve this type of claim. They referenced *Griffin v. United States*, in which the U.S. government was held liable because the Division of Biologics Standards of the National Institutes of Health released a batch of Sabin polio vaccine that did not conform to its own regulatory standards (the manufacturer settled), 351 F. Supp. 10 (E.D. Pa. 1972), *aff'd in part, rev'd in part and remanded*, 500 F.2d 1059 (3d Cir. 1974). And they also pointed to four cases in which manufacturers of quadrivalent vaccine (diphtheria, tetanus, pertussis, and poliomyelitis) were held liable because a new preservative activated the

pertussis component. *Tinnerhold v. Parke Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd* 411 F.2d 48 (2d Cir. 1969), *Stromsodt v. Parke Davis & Co.*, 257 F. Supp. 991 (D.N.D. 1966), *aff'd* 411 F.2d 1390 (8th Cir. 1969), *Vincent v. Thompson*, 361 N.Y.S.2d 282 (Sup. Ct. 1974), *rev'd in part*, 377 N.Y.S.2d 118 (App. Div. 2d Dep't 1975), and *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727 (2d Cir. 1979) (finding that plaintiff had introduced enough evidence to go to the jury on the issues of product defect or proximate causation against defendant manufacturer Quadrigen). *See also Vaccine Supply and Innovation* at 86.

The Act and its legislative history simply do not make sense without the understanding that the tort system remains an available alternative for such cases. And Congress' intent to keep the courthouse doors open is even more important today than it was in 1986.

B. The Compensation Program Is Not Working as Congress Intended, Making Recourse to Civil Court More Critical Than Ever.

Although Congress enacted the Act more than twenty years ago, the Compensation Program is not functioning as Congress intended. Already in 1999, Barbara Loe Fisher testified before Congress about why parents of vaccine-injured children were dissatisfied:

> There is bitter disappointment and pervasive unhappiness among parents...with the current structure and administration of the vaccine injury compensation program....[W]hen parents are unable to obtain financial assistance to care for a severely vaccine injured children, public faith in the mass vaccination system is further eroded.

Fisher Statement.

Parents of vaccine-injured children perceive vaccine court to be mean-spirited and hostile towards plaintiffs, experts and attorneys. Parents believe that vaccine court has a conflict of interests between protecting the vaccine program and compensating those injured by it. They observe that vaccine court will "protect the reputation of the current vaccine system at all costs – even if it means denying compensation to vaccine victims." *Id.* Vaccine court simply has not fulfilled its mission to compensate vaccine injury victims like Hannah Bruesewitz.

The overwhelming majority of cases in vaccine court today are "off-table," unable to take advantage of presumptive causation and thus require costly and time-consuming causation hearings, take years to litigate, are highly adversarial, and end without

compensation.[2] The most recent Omnibus Autism Proceeding, aggregating almost 5,000 claims of vaccine-induced autism, has no place in the statutory scheme Congress laid out for individual determinations of vaccine injury. *Cedillo v. Secretary of HHS*, 2009 WL 331968 (Fed. Cl. 2009); *Hazlehurst v. Secretary of HHS*, 2009 WL 332306 (Fed. Cl. 2009); *Snyder v. Secretary of HHS*, 2009 WL 332044 (Fed. Cl. 2009); *see also* Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 Am. U. L.Rev. 459, 484-90 (2008).

Furthermore, HHS has not expanded presumptions for recovery, as the 1986 Report recommended. H.R. Rep. 99-908 at 19-20, *reprinted in* 1986 U.S.C.C.A.N. at 6360-61. While the Center for Disease Control has added 46 doses of nine new vaccines for girls (43 doses of eight new vaccines for boys),[3] "no new signs, symptoms or injuries have

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[2] *See* National Vaccine Injury Compensation Program, Statistic Report (September 2, 2009) available at http://www.hrsa.gov/vaccinecompensation/statistics_report.htm showing that as of August 2009, 13,076 petitions have been filed and 2,344 have been compensated, or approximately 18%.

[3] Department of Health and Human Services, Centers for Disease Control and Prevention, Recommended Immunization Schedule for Persons 0 through 6 Years and 7 Through 18 Years (September 2, 2009) *available at* http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#printable, indicating nine new compulsory vaccines added since 1986: hepatitis B, rotavirus, *haemophilus influenzae* type b, pneumococcal, influenza, varicella, hepatitis A, meningococcal, human papillomavirus (for girls). Those that

been added to the Table of Injuries...– except anaphylaxis within four hours for the hepatitis B vaccine." Fisher Statement. In other words, HHS has not updated the Vaccine Injury Table's presumptions to correspond to today's substantially increased vaccine schedule.

Had the Bruesewitz family filed its initial claim one month earlier in 1995, Hannah's residual seizure disorder presumptively would have been compensated. However, in an administrative sleight of hand, HHS removed this presumption from the Vaccine Injury Table in March, 1995, forcing Hannah Bruesewitz and similar DPT-injured children to prove causation. 60 Fed. Reg. 7678 (Feb. 8, 1995); *see also Andreu v. Secretary of HHS*, 569 F.3d 1367, 1374 (2009). Fourteen years of litigation later, Hannah Bruesewitz has yet to receive one penny in federal compensation for vaccine injury.

By Congress' measure, vaccine court has failed. In its 1986 Report, the Committee wrote:

> The entire [vaccine court] proceeding...is to take place as expeditiously as possible and, in no case, should take more than one year....[W]ithout such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner.

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existed before 1986 were diphtheria, tetanus, pertussis, measles, mumps, rubella and inactivated poliovirus.

H.R. Rep. 99-908, at 17, *reprinted in* 1986 U.S.C.C.A.N. at 6358. *See also Compensating Vaccine Injuries: Are Reforms Needed?: Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources*, 106th Cong. (1999). It was to prevent the sort of injustice that Hannah Bruesewitz has suffered that Congress left petitioners free to reject the Compensation Program's findings "and go on to court." H.R. Rep. 99-908, at 12, *reprinted in* 1986 U.S.C.C.A.N. at 6353.

II. IN *BRUESEWITZ*, THE THIRD CIRCUIT ELIMINATED RIGHTS THAT CONGRESS EXPRESSLY PROTECTED.

While Congress wanted the Compensation Program to divert litigation from the traditional civil tort system, it never bestowed blanket immunity on vaccine manufacturers from all design defect claims. Congress preempted only those tort claims for "unavoidably unsafe" vaccines. Section 22(b)(1) states:

> [n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death ... if the injury or death resulted from side effects that were *unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

§ 300aa-22(b)(1) (emphasis added).

Congress explicitly imported the "unavoidable" language from comment k to § 402A of the Restatement (Second) of Torts, which applies only to "products which, in the present state of human knowledge, are quite incapable of being made safe." Restatement (Second) of Torts § 402A cmt. k (1965). To read Section 22 as preempting all design defect claims would effectively read the word "unavoidable" out of the statute. As Justices O'Connor and Breyer stated in a concurrence to an earlier case under this Act:

> [t]o the extent possible, we adhere to 'the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative. The construction adopted by the Court of Appeals contravenes this principle.

Shalala v. Whitecotton, 514 U.S. 268, 278 (1995) (O'Connor, J., concurring) (citations omitted).

Furthermore, Congress has subsequently authorized statutes, such as the Pandemic Preparedness Act, 42. U.S.C. § 247d-6d, for epidemic products that explicitly preempt all state laws that otherwise might apply. By contrast, the Act expressly preempts *state* statutes that prohibit civil actions against manufacturers for vaccine-related injuries. 42 U.S.C. § 300aa-22(e). Thus Congress was not silent on preemption of state tort remedies; the Act affirmatively preserved state contract and

tort remedies even in cases where states tried to extinguish them on their own.

The plain meaning and legislative history of the Act suggest only one plausible reading of § 22(b)(1): that manufacturers are free from liability for design defects if the injury that a victim suffered was "unavoidable."

This is the conclusion that two Circuit Courts of Appeal have previously reached. The Fourth Circuit in *Abbot v. Am. Cyanimid Co.*, 844 F.2d 1108 (4th Cir. 1988), held that federal law did not foreclose a plaintiff's defective design claims under Virginia law, even if an adequate warning was present. And the Fifth Circuit similarly found no preemption of state liability law for vaccine manufacturers. *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988). At odds with the Third Circuit, they reasoned that Congress intended for petitioners to be able to determine which vaccine side effects were unavoidable on a case-by-case basis under state common law.

There is nothing in the Act that prohibits vaccine-injured plaintiffs from putting design defect questions before a jury, so long as they meet all other substantive and procedural requirements. But other thresholds remain high in design defect cases, such as the requirements for putting scientific evidence before a jury.[4] Parents of vaccine-injured children

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[4] *See* Shah at 42, citing thimerosal cases in federal and state courts where defendant-manufacturers have succeeded in

believed then, and now, that the tort system provides a critical check to ensure that vaccines on the market are "the safest and most effective vaccines possible." 1986 Report, Part C.

A. The Third Circuit's Decision in *Bruesewitz* Departs From This Court's Precedent on Preemption.

The Court's recent decision in *Wyeth v. Levine*, reaffirming the long-standing presumption against federal preemption, bolsters the conclusion that the Third Circuit failed to follow this Court's precedent. 129 S. Ct. 1187, 1194 (2009) (quoting *Medtronic v.* Lohr, 518 U.S. 470, 485 (1996)). Earlier, in *Altria Group v. Good*, the Court explained that

> [this] assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States....Thus, when the text of a preemption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors preemption.

129 S. Ct. 538, 543 (2008) (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). Absent

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having courts dismiss plaintiffs' claims under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) and *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) standards of evidence before trial on grounds of scientific implausibility.

explicit language barring design defect claims, the Third Circuit should have allowed Hannah Bruesewitz her day in court.

The Georgia Supreme Court in *American Home Products v. Ferrari* unanimously held that § 22 of the Act does not preempt all design defect claims, but only those side effects that were unavoidable. 284 Ga. 384, 386 (2008). Applying *Bates* to resolve the ambiguity in § 22, the *Ferrari* court opined that "[I]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed its intent more clearly." 284 Ga. at 393. The *Ferrari* court looked carefully at Congress' intent, expressed in the Act and in the 1987 amendments to fund the program. It wrote:

> We hesitate to hold that a manufacturer is excused from making changes it knows will improve its product merely because an older, more dangerous version received FDA approval....[To do so] "would 'have the perverse effect of granting complete [tort] immunity from design defect liability to an entire industry'."

284 Ga. at 394 (citations omitted).

To square *Bruesewitz* with the Court's preemption decisions, the Court should find the Act does not imply preemption. The Act permits petitioners to bring design defect claims to court, and

manufacturers may then rebut those claims by showing that any injuries from its design were unavoidable.

This Court should grant *certiorari* and reverse the Third Circuit's decision that rewrites the agreement that Congress, parents, manufacturers and physicians painstakingly reached in 1986.

CONCLUSION

For the foregoing reasons, and those stated in the petition, the writ of *certiorari* should be granted, and the judgment below reversed.

Mary S. Holland
245 Sullivan St.
New York, N.Y.
(212) 998-6212

Counsel for Amici Curiae

September 8, 2009

JOINT APPENDIX

No. 09-152

Supreme Court, U.S.
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IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

JOINT APPENDIX (Corrected)

KATHLEEN M. SULLIVAN
Counsel of Record
FAITH E. GAY
SANFORD I. WEISBURST
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000
(kathleensullivan@quinnemanuel.com)

Counsel for Respondent

DAVID C. FREDERICK
Counsel of Record
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

Counsel for Petitioners

May 24, 2010

(Additional Counsel Listed On Inside Cover)

PETITION FOR A WRIT OF CERTIORARI FILED: AUGUST 4, 2009
CERTIORARI GRANTED: MARCH 8, 2010

DANIEL J. THOMASCH
RICHARD W. MARK
E. JOSHUA ROSENKRANZ
LAUREN J. ELLIOT
JOHN L. EWALD
ORRICK, HERRINGTON &
SUTCLIFFE LLP
51 West 52nd Street
New York, New York 10019-6142
(212) 506-5000

Counsel for Respondent

COLLYN A. PEDDIE
THE LAW OFFICES OF
COLLYN PEDDIE
440 Louisiana, Suite 1710
Houston, Texas 77002-1689
(713) 422-1205

JOHN T. BOUNDAS
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway
Suite 600
Houston, Texas 77017-5051
(713) 230-2200

Counsel for Petitioners

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UNITED STATES COURT OF FEDERAL CLAIMS

Case No. 1:95-vv-00266-UNJ

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ,
Petitioners,

v.

SECRETARY OF HEALTH & HUMAN SERVICES,
Respondent.

CIVIL DOCKET

DATE FILED	#	DOCKET TEXT
4/3/95	1	PETITION by RUSSELL BRUESEWITZ and ROBALEE BRUESEWITZ, FILING FEE $120, RECEIPT #38953. Vac. Date: 4.1.92, (Respondent's report due 7/3/95) (FE) (Entered: 04/04/1995)
		* * * * *
9/17/97	42	ORDER informing petitioners that they have until 10/17/97 to file their notice choosing to continue or withdraw the petition. (signed by Special Master John F. Edwards) Copy to parties. (DS) (Entered: 09/24/1997)
		* * * * *

9/23/97	44	Notice of filing election to remain in program by RUSSELL BRUESEWITZ and ROBALEE BRUESEWITZ. Service: 9/22/97. (HW) (Entered: 09/26/1997)
		* * * * *
3/26/02		Evidentiary Hearing held (Transcript due 4/25/02) (DS) (Entered: 04/03/2002)
		* * * * *
8/21/02	119	TRANSCRIPT of proceedings re: 1 volume, at Washington, D.C., for date of July 23, 2002. Notice to parties. (FE) (Entered: 08/22/2002)
		* * * * *
12/20/02	122	Decision of Special Master Laura D. Millman. Copy to parties. (DS) (Entered: 12/29/2002)
1/27/03	123	JUDGMENT pursuant to Vaccine Rule 11(a), that the petition is dismissed with prejudice. (signed by Clerk). Copy to parties. (DAL) (Entered: 01/27/2003)
1/27/03		Case closed. (DAL) (Entered: 01/27/2003)
2/14/03	124	Notice of election to file civil action by RUSSELL BRUESEWITZ. Service: 2/14/03. (LTD) (Entered: 02/25/2003)
		* * * * *
5/16/03	126	MOTION for Attorney Fees by ROBALEE BRUESEWITZ, RUSSELL BRUESEWITZ. Service: 05/16/03.

Response due by 6/2/2003 (jmm) (Entered: 05/23/2003)

* * * * *

8/6/04 130 DECISION on Attorney's Fees and Costs Signed by Special Master Laura D. Millman. (tjk) (Entered: 08/10/2004)

8/16/04 131 JOINT NOTICE Not to Seek Review by ROBALEE BRUESEWITZ, RUSSELL BRUESEWITZ, SECRETARY OF HEALTH AND HUMAN SERVICES re [130] DECISION of Special Master – Fees. (tjk) (Entered: 08/19/2004)

8/20/04 132 JUDGMENT entered, pursuant to Vaccine Rule 11(a), that petitioners are awarded attorneys' fees and costs in the amount of $126,800.00, payable in the form of two checks. The first check shall be for $1,800.00 made payable to the petitioners and the second check for $125,000.00 shall be made jointly payable to the petitioners and Mr. Clifford Shoemaker. (lld) (Entered: 08/20/2004)

8/27/04 133 Petitioner's Election to Accept [132] Judgment on Attorney Fees. Service: 8/27/04. (jat) (Entered: 08/31/2004)

11/5/04 134 SATISFACTION OF JUDGMENT in the amount of $1,800.00, was mailed to Clifford Shoemaker, Esquire, attorney for the petitioners. See letter in file. (bre) (Entered: 11/30/2004)

11/5/04 135 SATISFACTION OF JUDGMENT in the amount of $125,000.00,

was mailed to Clifford Shoemaker, Esquire, attorney for the petitioners. See letter in file. (bre) (Entered: 11/30/2004)

PHILADELPHIA COUNTY
COURT OF COMMON PLEAS

No. 001272

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

CIVIL DOCKET REPORT

* * * * *

Docket Entries

Filing Entry Date	Docket Type
12-OCT-2005	ACTIV – ACTIVE CASE
12-OCT-2005	CIVIJ – COMMENCEMENT CIVIL ACTION JURY
12-OCT-2005	JURYT – JURY TRIAL PERFECTED
12-OCT-2005	CMPLT – COMPLAINT FILED NOTICE GIVEN

Docket Entry: COMPLAINT WITH NOTICE TO DEFEND WITHIN TWENTY (20) DAYS AFTER SERVICE IN ACCORDANCE WITH RULE 1018.1 FILED.

* * * * *

15-NOV-2005 RMEDC – NOT OF REMOVAL TO US DIST CT

Docket Entry: NOTICE OF REMOVAL TO THE U.S. (EASTERN) DISTRICT COURT UNDER 05-CV-5994 FILED. BTP

* * * * *

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA
(PHILADELPHIA)

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

CIVIL DOCKET

DATE FILED	#	DOCKET TEXT
11/15/05	1	NOTICE OF REMOVAL by WYETH, INC. from Philadelphia CCP, case number October 2005 No. 1272. (Filing fee $250 receipt number 923325), Certificate of Service. (tj) (Entered: 11/16/2005)
11/22/05	2	ANSWER to Complaint together with Affirmative Defenses with Jury Demand and Certificate of Service by WYETH, INC. (Attachments: #1 Cer-

tificate of Service) (DANDORA, REETU) (Entered: 11/22/2005)

* * * * *

12/13/05 4 MOTION to Remand to State Court filed by ROBALEE BRUESEWITZ. Motion to Remand with Certificate of Service. (Attachments: #1 Supplement Memorandum of Law in Support of Motion to Remand #2 Exhibit Exhibits to Motion to Remand part 1 #3 Exhibit Exhibits to Motion to Remand part 2) (BYRNE, JAMES) (Entered: 12/13/2005)

12/27/05 5 RESPONSE in Opposition re 4 MOTION to Remand to State Court filed by WYETH, INC. (Attachments: #1 Exhibit 1 #2 Exhibit 2, Part 1 #3 Exhibit 2, Part 2 #4 Certificate of Service) (DANDORA, REETU) (Entered: 12/27/2005)

* * * * *

1/10/06 8 Memorandum of Law in Support of REPLY to Response to Motion re 4 MOTION to Remand to State Court filed by RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ, Certificate of Service. (BYRNE, JAMES) Modified on 1/11/2006 (np). (Entered: 01/10/2006)

* * * * *

1/23/06 10 MOTION for Leave to File a Sur-Reply in Opposition of Plaintiffs' Motion to Remand filed by WYETH,

		INC. Certificate of Service. (Attachments: #1 Exhibit A #2 Certificate of Service) (DANDORA, REETU) (Entered: 01/23/2006)
		* * * * *
3/27/06	13	MEMORANDUM AND ORDER THAT PLAINTIFFS' MOTION TO REMAND IS DENIED. DEFENDANT'S MOTION TO FILE A SUR-REPLY IS GRANTED. SIGNED BY JUDGE MICHAEL M. BAYLSON ON 03/27/06. 03/27/06 ENTERED AND COPIES MAILED AND E-MAILED. (ac) (Entered: 03/27/2006)
3/27/06	14	Sur-Reply of Defendant in Further Opposition to Plaintiffs' Motion to Remand filed by WYETH, INC. (See Paper No. 10 for PDF Attachment) (ac) Additional attachment(s) added on 9/20/2007 (ac). (Entered: 03/27/2006)
		* * * * *
6/13/06	22	First MOTION for Summary Judgment of Defendant Wyeth, Inc. filed by WYETH, INC. Statement of Undisputed Facts In Support of Its Motion for Summary Judgment, Brief, Index of Exhibits and Certificate of Service. (Attachments: #1 Text of Proposed Order Order Upon Consideration of the Motion for Summary Judgment of Defendant Wyeth, Inc. #2 Exhibit Exhibit 1 #3 Exhibit Exhibit 2 #4 Exhibit Exhibit 3 #5 Exhibit

Exhibit 4 #6 Exhibit Exhibit 5 #7 Errata Exhibit 6 #8 Exhibit Exhibit 7 #9 Exhibit Exhibit 8 #10 Exhibit Exhibit 9 #11 Exhibit Exhibit 10 #12 Exhibit Exhibit 11 #13 Exhibit Exhibit 12) (DANDORA, REETU) (Entered: 06/13/2006)

* * * * *

7/11/06 29 RESPONSE to Motion re 22 First MOTION for Summary Judgment of Defendant Wyeth, Inc. filed by RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ, Memorandum, Certificate of Service. (CURRAN, ROBERT) Modified on 7/13/2006 (np). (Entered: 07/11/2006)

* * * * *

7/25/06 32 REPLY to Response to Motion re 22 First MOTION for Summary Judgment of Defendant Wyeth, Inc. filed by WYETH, INC., Certificate of Service. (DANDORA, REETU) Modified on 7/26/2006 (np). (Entered: 07/25/2006)

* * * * *

1/31/07 44 Statement of Contentions by RUSSELL BRUESEWITZ, Certificate of Service. (FABRY, JOHN) Modified on 2/1/2007 (np). (Entered: 01/31/2007)

* * * * *

2/1/07 55 Statement Amended Statement of Contentions by ROBALEE BRUE-

SEWITZ. (FABRY, JOHN) (Entered: 02/01/2007)

* * * * *

2/15/07 59 Response in Opposition to re 55 Statement of Plaintiffs' Amended Contentions by WYETH, INC., CERTIFICATE OF SERVICE. (Attachments: #1 Exhibit A) (DANDORA, REETU) Modified on 2/16/2007 (afm). (Entered: 02/15/2007)

* * * * *

2/22/07 65 MEMORANDUM AND ORDER THAT DEFENDANT WYETH'S MOTION FOR SUMMARY JUDGMENT IS DENIED WITHOUT PREJUDICE. SIGNED BY JUDGE MICHAEL M. BAYLSON ON 02/22/07. 02/22/07 ENTERED AND COPIES E-MAILED. COPIES FAXED BY CHAMBERS. (ac) (Entered: 02/22/2007)

* * * * *

3/7/07 67 MOTION for Leave to File Plaintiffs' First Amended Complaint and Jury Demand filed by RUSSELL BRUESEWITZ, CERTIFICATE OF SERVICE (FIRST AMENDED COMPLAINT ATTACHED). (Attachments: #1 Text of Proposed Order Order Granting Plaintiffs' Motion for Leave to File Amended Complaint #2 Plaintiffs' First Amended Complaint and Jury Demand) (FABRY, JOHN)

Modified on 3/8/2007 (afm). (Entered: 03/07/2007)

* * * * *

3/19/07	71	Plaintiffs' Memorandum of Law In Support of Their Motion for Leave to Amend filed by RUSSELL BRUESEWITZ. CERTIFICATE OF SERVICE. (Attachments: #1 Exhibit Exhibit A #2 Exhibit Exhibit B) (FABRY, JOHN) Modified on 3/20/2007 (afm). (Entered: 03/19/2007)

* * * * *

4/2/07	73	RESPONSE in Opposition re 67 MOTION for Leave to File Plaintiffs' First Amended Complaint and Jury Demand filed by WYETH, INC., CERTIFICATE OF SERVICE. (Attachments: #1 Text of Proposed Order #2 Index of Exhibits #3 Exhibit 1 (Part 1) #4 Exhibit 1 (Part 2) #5 Exhibit 2 #6 Exhibit 3 #7 Exhibit 4 #8 Certificate of Service) (DANDORA, REETU) Modified on 4/3/2007 (afm). (Entered: 04/02/2007)
4/2/07	74	Declaration re 73 Response in Opposition to Motion, of Mary B. Ritchey by WYETH, INC. (Attachments: #1 Exhibit A #2 Exhibit B (Part 1) #3 Exhibit B (Part 2) #4 Exhibit C #5 Exhibit D #6 Exhibit E #7 Exhibit F) (DANDORA, REETU) (Entered: 04/02/2007)

4/3/07	75	EXHIBIT 1 TO THE DECLARATION OF MARY B. RITCHEY BY WYETH, INC. (FILED UNDER SEAL) (ac) (Entered: 04/03/2007)
4/3/07	76	EXHIBIT 2 TO THE DECLARATION OF MARY B. RITCHEY BY WYETH, INC. (FILED UNDER SEAL) (ac) (Entered: 04/03/2007)

* * * * *

4/9/07	78	Plaintiffs' Memorandum of Law In Support of Their Motion for Leave to Amend re 71 MOTION for Leave to File filed by RUSSELL BRUESEWITZ. (FABRY, JOHN) Modified on 4/10/2007 (np). (Entered: 04/09/2007)

* * * * *

4/18/07	80	MEMORANDUM AND ORDER THAT THE COURT WILL GRANT LEAVE TO PLAINTIFFS TO FILE THE AMENDMENT. WYETH SHALL FILE AN ANSWER, ETC. PLAINTIFFS WILL HAVE SIXTY DAYS FROM THE DATE OF THIS ORDER TO FILE A RESPONSE TO THE NEW MOTION FOR SUMMARY JUDGMENT ATTACKING COUNT IV OF THE AMENDED COMPLAINT, AND ON ANY OTHER GROUNDS ON WHICH WYETH WILL HAVE FILED A MOTION. WYETH WILL HAVE FOURTEEN DAYS TO FILE A REPLY BRIEF. AT THIS TIME, THE COURT WILL DESIGNATE WYETH'S PREVIOUS-

		LY DENIED MOTION FOR SUMMARY JUDGMENT AS REFILED, BUT LIMITED TO COUNTS I-III OF THE AMENDED COMPLAINT ON THE ISSUE OF PREEMPTION. SIGNED BY JUDGE MICHAEL M. BAYLSON ON 04/18/07. 04/19/07 ENTERED AND COPIES E-MAILED. COPIES MAILED AND FAXED BY CHAMBERS 04/18/07. (ac) (Entered: 04/19/2007)
		* * * * *
5/8/07	84	NOTICE by WYETH, INC. of its Answer and Affirmative Defenses to Plaintiff's First Amended Complaint and Jury Demand (DANDORA, REETU) (Entered: 05/08/2007)
		* * * * *
5/18/07	88	Third MOTION for Summary Judgment Pursuant to FEDERAL RULES OF CIVIL PROCEDURE 56(b) filed by WYETH, INC. Memorandum of Law, Declarations, Certificate of Service. (Attachments: #1 Text of Proposed Order #2 Statement of Undisputed Facts #3 Memorandum of Law #4 Index of Exhibits #5 Exhibit A #6 Exhibit B #7 Exhibit C #8 Exhibit D #9 Exhibit E #10 Exhibit F #11 Certificate of Service) (DANDORA, REETU) Modified on 5/22/2007 (fh) (Entered: 05/18/2007)
5/18/07	89	Declaration re 88 Third MOTION for Summary Judgment (of Dennis Foley,

		Ph.D.) by WYETH, INC. (Attachments: #1 Exhibit A #2 Exhibit B #3 Exhibit C #4 Exhibit D #5 Exhibit E #6 Exhibit F #7 Exhibit G #8 Exhibit H #9 Exhibit I #10 Exhibit J) (DANDORA, REETU) (Exhibits "B" and "D" filed under seal) Modified on 5/23/2007 (fdc). (Entered: 05/18/2007)
5/18/07	90	Declaration re 88 Third MOTION for Summary Judgment (of Jill Hackell) by WYETH, INC. (Attachments: #1 Exhibit A #2 Exhibit B #3 Exhibit C #4 Exhibit D #5 Exhibit E) (DANDORA, REETU) (Entered: 05/18/2007)
5/18/07	91	EXHIBIT 1 TO THE DECLARATION OF DENNIS J. FOLEY, PH.D. BY WYETH, INC. (FILED UNDER SEAL) (ac) (Entered: 05/21/2007)
5/18/07	92	EXHIBIT 2 TO THE DECLARATION OF DENNIS J. FOLEY, PH.D. BY WYETH, INC. (FILED UNDER SEAL) (ac) (Entered: 05/21/2007)

* * * * *

6/19/07	95	EXHIBITS A THROUGH K TO PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT WYETH, INC.'S THIRD MOTION FOR SUMMARY JUDGMENT AND IN FURTHER OPPOSITION TO WYETH'S PENDING MOTIONS FOR SUMMARY JUDGMENT BY RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ. (FILED UNDER SEAL) (ac) (Entered: 06/19/2007)

6/19/07	102	Plaintiffs' Opposition to Defendant Wyeth, Inc.'s Third Motion for Summary Judgment Further Opposition to Wyeth's Pending Motion for Summary Judgment, Objections and Motion to Strike filed by RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ, Memorandum, Certificate of Service. (ac) (Entered: 10/03/2007)

* * * * *

7/10/07	97	RESPONSE in Support re 88 Third MOTION for Summary Judgment Pursuant to FEDERAL RULES OF CIVIL PROCEDURE 56(b) Third MOTION for Summary Judgment Pursuant to FEDERAL RULES OF CIVIL PROCEDURE 56(b) AND ALL PENDING MOTIONS FOR SUMMARY JUDGMENT filed by WYETH, INC., CERTIFICATE OF SERVICE. (Attachments: #1 Exhibit 1) (DANDORA, REETU) Modified on 7/12/2007 (afm). (Entered: 07/10/2007)

* * * * *

8/24/07	99	MEMORANDUM AND ORDER THAT DEFENDANT'S MOTIONS FOR SUMMARY JUDGMENT ARE GRANTED. JUDGMENT IS ENTERED IN FAVOR OF DEFENDANT AND AGAINST PLAINTIFFS. THE CLERK SHALL CLOSE THIS CASE. SIGNED BY JUDGE MICHAEL M. BAYLSON ON 08/24/07. 08/27/07 ENTERED AND COPIES MAILED

		AND E-MAILED. (ac) (Entered: 08/27/2007)
9/19/07	100	NOTICE OF APPEAL by RUSSELL BRUESEWITZ. Copies to Judge, Clerk USCA, Appeals Clerk and JOHN R. FABRY, Certificate of Service. (FABRY, JOHN) Modified on 9/20/2007 (nd). (Entered: 09/19/2007)
9/19/07	101	Clerk's Notice to USCA re: Notice of Appeal. (ac) Additional attachment(s) added on 9/20/2007 (ac). (Entered: 09/20/2007)
9/20/07		USCA Appeal Fees received $455 receipt number 400 942349 re: Notice of Appeal filed by RUSSELL BRUESEWITZ. (ac) (Entered: 09/20/2007)
9/26/07		NOTICE of Docketing Record on Appeal from USCA re: Notice of Appeal filed by RUSSELL BRUESEWITZ. USCA Case Number 07-3794 (ac) (Entered: 09/27/2007)
5/21/09	103	ORDER of USCA that upon consideration whereof, it is now hereby ADJUDGED and ORDERED that the judgment of the District Court entered August 27, 2007 be and the same is hereby affirmed. Costs taxed against the appellant. All of above in accordance with opinion of this Court. (ti) (Entered: 05/21/2009)

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

GENERAL DOCKET

DATE	DOCKET ENTRY
9/24/07	CIVIL CASE DOCKETED. Notice filed by Russell Bruesewitz and Robalee Bruesewitz. (MB)
	* * * * *
1/22/08	ELECTRONIC BRIEF on behalf of Appellants Russell Bruesewitz and Robalee Bruesewitz, Copies: 1, Pages: 30, Word Count: 10,631, delivered by mail, filed. Certificate of service date 1/22/08. (LAL)
1/22/08	HARD COPY RECEIVED from Appellants Robalee Bruesewitz and Russell Bruesewitz – 1st Step Brief with

Volume I of Appendix attached. Copies: 10. (GPK)

1/22/08 1st STEP APPENDIX on behalf of Appellants Robalee Bruesewitz and Russell Bruesewitz, filed. Copies: 4. Volumes: 4 (volume I attached to brief, volume IV held UNDER SEAL pending further order of the Court). Manner of Service: mail. Certificate of Service dated 01/22/2008. (GPK)

* * * * *

2/21/08 ELECTRONIC 2nd STEP BRIEF on behalf of Appellee Wyeth Inc. filed. Pages: 58, Words: 13,669, Manner of Service: mail, Certificate of Service dated 02/21/2008. (LAL)

2/22/08 HARD COPY RECEIVED from Appellee Wyeth Inc – 2nd Step Brief with Supplemental Appendix attached. Copies: 10. (LAL)

2/22/08 MOTION filed by Appellee Wyeth Inc. for Leave to File Supplemental Appendix. Response due on 03/04/2008. Certificate of Service dated 02/21/2008. (LAL)

3/7/08 ELECTRONIC 3rd STEP BRIEF on behalf of Appellants Robalee Bruesewitz and Russell Bruesewitz, filed. Pages: 15, Manner of Service: mail, Certificate of Service dated 03/07/2008. (LAL)

3/7/08 HARD COPY RECEIVED from Appellants Robalee Bruesewitz and Russell

Bruesewitz – 3rd Step Brief. Copies: 10. (EAF)

3/14/08 CLERK ORDER granting Motion to file supplemental appendix filed by Appellee Wyeth Inc. filed. (LAL)

3/14/08 SUPPLEMENTAL APPENDIX on behalf of Appellee Wyeth Inc. filed. Copies: 4. Volumes: 2 (volume I attached to brief). Manner of Service: mail, Certificate of Service dated 02/21/2008. (LAL)

* * * * *

9/11/08 ARGUED on Thursday, 09/11/2008 before McKEE, SMITH and WEIS, Circuit Judges (Participated via video conference) Richard W. Mark arguing for Appellee Wyeth Inc.; Collyn A. Peddie arguing for Appellants Russell Bruesewitz and Robalee Bruesewitz (TLW)

10/9/08 LETTER dated 10/08/2008 filed pursuant to Rule 28(j) from counsel for Appellants Robalee Bruesewitz and Russell Bruesewitz. SEND TO MERITS PANEL. (MB)

10/15/08 RESPONSE on behalf of Appellee Wyeth Inc. to Appellant's Rule 28(j) letter, filed. Certificate of Service dated 10/15/2008. (MB)

* * * * *

3/27/09 PRECEDENTIAL OPINION Coram: MCKEE, SMITH and WEIS, Circuit

Judges. Total Pages: 52. Judge: SMITH Authoring. (MB)

3/27/09 JUDGMENT, Affirmed. Costs taxed against Appellant. (MB)

* * * * *

4/24/09 ECF FILER: Petition filed by Appellants Robalee Bruesewitz and Russell Bruesewitz for Rehearing before Original Panel and Court En Banc. Certificate of Service dated 04/24/2009. (CAP)

5/6/09 ORDER (SCIRICA, Chief Judge, SLOVITER, MCKEE, RENDELL, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN and *WEIS, Circuit Judges) denying En Banc and Original Panel Rehearing filed by Appellants Russell Bruesewitz and Robalee Bruesewitz, filed. D. Brooks Smith, Authoring Judge.

*The vote of the Honorable Joseph F. Weis, Jr., Senior Circuit Judge of the United Sates Court of Appeals for the Third Circuit, is limited to panel rehearing. (MB)

5/6/09 ECF FILER: Motion filed by Appellants Robalee Bruesewitz and Russell Bruesewitz to stay mandate. Certificate of Service dated 05/06/2009. (CAP)

5/14/09 ORDER (MCKEE, SMITH and WEIS, Circuit Judges) denying Motion to stay mandate filed by Appellants Russell Bruesewitz and Robalee Bruesewitz,

	filed. D. Brooks Smith, Authoring Judge. (MB)
5/20/09	MANDATE ISSUED, filed. (TRG)
8/10/09	NOTICE from U.S. Supreme Court. Petition for Writ of Certiorari filed by Russell Bruesewitz on 08/04/2009. Supreme Court Case No. 09-152. (CRG)
3/8/10	NOTICE of U.S. Supreme Court disposition at No. 09-152. Petition for Writ of Certiorari filed by Russell Bruesewitz granted on 03/08/2010. (CRG)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

[Filed June 13, 2006]

DEFENDANT WYETH, INC.'S BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT PURSUANT TO FED. R. CIV. P. 56(b)

[TEXT OMITTED]

EXHIBIT 8

CDC

[Graphics Omitted]

MMWR

Weekly

December 20, 1991 / 40(50);881-882

Food and Drug Administration Approval of Use of Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine

The Immunization Practices Advisory Committee (ACIP) and the Committee on Infectious Diseases, American Academy of Pediatrics, recommend that children routinely receive a series of five doses of vaccine against diphtheria, tetanus, and pertussis before 7 years of age (1,2). The Food and Drug Administration has approved a diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) prepared by Lederle Laboratories (Pearl River, New York) and distributed as ACEL-IMUNETM*. This vaccine is licensed only for use as the fourth and fifth doses for children who have previously been vaccinated against diphtheria, tetanus, and pertussis with three doses of whole-cell diphtheria and tetanus toxoids and pertussis vaccine (DTP) and is not licensed for the initial three-dose series in infants and children; whole-cell DTP should continue to be used for these initial doses. Whole-cell DTP continues to be an acceptable alternative for the fourth and fifth doses. DTaP is not licensed for use in children less than 15 months of age or after the seventh birthday. The fourth dose should be given at least 6 months after the third dose of whole-cell DTP and is usually

administered to children 15-18 months of age (1,2). A dose of DTaP may be given as the fifth dose in the series for children aged 4-6 years who have received either all four prior doses as whole-cell vaccine or three doses of whole-cell DTP plus one dose of DTaP; this fifth dose should be given before the child enters kindergarten or elementary school. The fifth dose in the vaccination series is not necessary if the fourth dose was given on or after the fourth birthday (1,2).

The following evidence supports the use of ACEL-IMUNETM after the initial three-dose series of whole-cell DTP vaccine in infants:

1. The immunogenicity of the antigens comprising ACEL-IMUNETM when used for the fourth and fifth doses is comparable to that of whole-cell DTP vaccine (3).

2. Although not evaluated in a prospective study in which clinicians and investigators were blinded with respect to the vaccination status of the study subjects, the effectiveness against clinical pertussis disease of a DTaP vaccine manufactured and used in Japan (which contained a pertussis vaccine component identical to that in ACEL-IMUNETM) has been demonstrated in children greater than or equal to 2 years of age (4).

3. The rates of local reactions, fever, and other common systemic symptoms following receipt of ACEL-IMUNETM inoculations are lower than those following whole-cell DTP vaccination (3). A statement from ACIP will be published as an MMWR Recommendations and Reports (5). Reported by: Center for Biologics Evaluation

and Research, Food and Drug Administration. National Center for Prevention Svcs, CDC.

References

1. ACIP. Diphtheria, tetanus, and pertussis: recommendations for vaccine use and other preventive measures--recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1991;40(no. RR-10).

2. American Academy of Pediatrics. Report of the Committee on Infectious Diseases. Elk Grove Village, Illinois: American Academy of Pediatrics, Committee on Infectious Diseases, 1991.

3. Blumberg DA, Mink CM, Cherry JD, et al. Comparison of an acellular pertussis component diphtheria-tetanus-pertussis (DTP) vaccine with a whole-cell pertussis-component DTP vaccine in 17- to 24-month-old children, with measurement of 69-kilodalton outer membrane protein antibody. J Pediatr 1990;117:46-51.

4. Mortimer EA, Kimura M, Cherry JD, et al. Protective efficacy of the Takeda acellular pertussis vaccine combined with diphtheria and tetanus toxoids following household exposure of Japanese children. Am J Dis Child 1990;144:899-904.

5. ACIP. Pertussis vaccination: acellular pertussis vaccine for reinforcing and booster use--supplementary Immunization Practices Advisory Committee (ACIP) statement. MMWR (in press).

Table 2. Recommended schedule for active immunization of normal infants and children*

Recommended age†	Vaccine(s)§	Comments
2 mos	DTP#1¶, OPV#1**	OPV and DTP can be given earlier in areas of high endemicity
4 mos	DTP#2, OPV#2	6-wk to 2-mo interval desired between OPV doses
6 mos	DTP#3	An additional dose of OPV at this time is optional in areas with a high risk of poliovirus exposure
15 mos††	MMR§§, DTP#4, OPV#3	Completion of primary series of DTP and OPV
18 mos	HbCV¶¶	Conjugate preferred over polysaccharide vaccine***
4-6 years	DTP#5†††, OPV#4	At or before school entry
14-16 years	Td§§§	Repeat every 10 yrs throughout life

* See Table 3 for the recommended immunization schedules for infants and children up to their seventh birthday not immunized at the recommended times.

† These recommended ages should not be construed as absolute, e.g., 2 months can be 6-10 weeks. However, MMR should not be given to children <12 months of age. If exposure to measles disease is considered likely, then children 6 through 11 months old may be immunized with single-antigen measles vaccine. These children should be immunized with MMR when they are approximately 15 months of age.

§ For all products used, consult the manufacturers' package enclosures for instructions regarding storage, handling, dosage, and administration. Immunobiologics prepared by different manufacturers can vary, and those of

the same manufacturer can change from time to time. The package inserts are useful references for specific products, but they may not always be consistent with current ACIP and American Academy of Pediatrics immunization schedules.

¶ DTP = Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed. DTP may be used up to the seventh birthday. The first does can be given at 6 weeks of age and the second and third doses given 4-8 weeks after the preceding dose.

** OPV = Poliovirus Vaccine Live Oral, Trivalent: contains poliovirus types 1, 2, and 3.

++ Provided at least 6 months have elapsed since DTP #3 or, if fewer than 3 doses of DTP have been received, at least 6 weeks since the last previous dose of DTP or OPV. MMR vaccine should not be delayed to allow simultaneous administration with DTP and OPV. Administering MMR at 15 months and DTP #4 and OPV #3 at 18 months continues to be an acceptable alternative.

§§ MMR = Measles, Mumps, and Rubella Virus Vaccine, Live. Counties that report >5 cases of measles among preschool children during each of the last 5 years should implement a routine 2-dose measles vaccination schedule for preschoolers. The first does should be administered at 9 months or the first health-care contact thereafter. Infants vaccinated before their first birthday should receive a second dose at about 15 months of age. Single-antigen measles vaccine should be used for children aged <1 year and MMR for children vaccinated on or after their first birthday. If resources do not allow a routine 2-dose schedule, an acceptable alternative is to lower the routine age for MMR vaccination to 12 months.

¶¶ HbCV = Vaccine composed of Haemophilus influenzae b polysaccharide antigen conjugated to a protein carrier. Children <5 years of age previously vaccinated with polysaccharide vaccine between the ages of 18 and 23 months should be revaccinated with a single dose of conjugate vaccine if at least 2 months have elapsed since the receipt of the polysaccharide vaccine.

*** If HbCV is not available, an acceptable alternative is to give Haemophilus influenzae b polysaccharide vaccine (HbPV) at age >24 months. Children at high risk for *Haemophilus influenzae* type b disease where conjugate vaccine is not available may be vaccinated with HbPV at 18 months of age and revaccinated at 24 months.

+++ Up to the seventh birthday.

EXHIBIT 9

CDC

[Graphics Omitted]

MMWR

Weekly

August 28, 1992 / 41(34);630-631

Food and Drug Administration Approval of a Second Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine

The Advisory Committee for Immunization Practices (ACIP) and the Committee on Infectious Diseases, American Academy of Pediatrics (AAP), recommend that children routinely receive a series of five doses of vaccine against diphtheria, tetanus, and pertussis before age 7 years (1,2). On December 17, 1991, the Food and Drug Administration (FDA) approved a diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) prepared and distributed by Lederle Laboratories (Pearl River, New York) as ACEL-IMUNE\T* (3). On February 7, 1992, ACIP issued a supplementary statement on the use of DTaP (4), and the AAP did so on April 15 (5).

On August 21, 1992, the FDA approved licensure of a second DTaP product, prepared and distributed as Tripedia\T by Connaught Laboratories, Inc. (Swiftwater, Pennsylvania). As with ACEL-IMUNE\T, Tripedia\T is licensed only for use as the fourth and/or fifth dose(s) for children aged 15 months through 6 years (i.e., before the seventh birthday) who have previously been vaccinated against diphtheria, tetanus, and pertussis with three doses of

whole-cell diphtheria and tetanus toxoids and pertussis vaccine (DTP) and is not licensed for the initial three-dose series in infants and children; whole-cell DTP should continue to be used for these initial doses. Whole-cell DTP continues to be an acceptable alternative for the fourth and/or fifth dose(s).

The following evidence supports the use of Tripedia\T after the initial three-dose series of whole-cell DTP in infants:

1. The immunogenicity of the antigens that make up Tripedia\T

when used for the fourth and fifth doses is comparable to that of whole-cell DTP (unpublished manufacturer's data).

2. A randomized, placebo-controlled clinical efficacy trial in Sweden in 1985-1987 demonstrated efficacy when two doses of a pertussis vaccine similar to the formulation in Tripedia\T were given to children starting at ages 5-11 months (an age older than that recommended for initiating whole-cell DTP vaccination in the United States) (6).

3. The rates of local reactions, fever, and other common systemic symptoms following receipt of Tripedia\T inoculations when used for the fourth and fifth doses are lower than those following whole-cell DTP vaccination (unpublished manufacturer's data). An updated statement from ACIP will be issued as an MMWR Recommendations and Reports (7).

Reported by: Center for Biologics Evaluation and Research, Food and Drug Administration. National Center for Prevention Svcs, CDC.

References

1. ACIP. Diphtheria, tetanus, and pertussis: recommendations for vaccine use and other preventive measures--recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1991;40(no. RR-l0).

2. American Academy of Pediatrics. Report of the Committee on Infectious Diseases. Elk Grove Village, Illinois: American Academy of Pediatrics, Committee on Infectious Diseases, 1991.

3. CDC. Food and Drug Administration approval of use of diphtheria and tetanus toxoids and acellular pertussis vaccine. MMWR 1991; 40:881-2.

4. ACIP. Pertussis vaccination: acellular pertussis vaccine for reinforcing and booster use--supplementary ACIP statement: recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1992;41(no. RR-1).

5. Committee on Infectious Diseases, American Academy of Pediatrics. Acellular pertussis vaccines: recommendations for use as the fourth and fifth doses. Pediatrics 1992;90:121-3.

6. Ad Hoc Group for the Study of Pertussis Vaccines. Placebo-controlled trial of two acellular pertussis vaccines in Sweden – protective efficacy and adverse events. Lancet 1988;1:955-60.

7. ACIP. Pertussis vaccination: acellular pertussis vaccine for the fourth and fifth doses of the DTP series -- update to supplementary ACIP statement: recommendations of the Advisory Committee for Immunization Practices (ACIP). MMWR 1992 (in press).

EXHIBIT 10

CDC

[Graphics Omitted]

MMWR

Weekly

August 9, 1996 / 45(31);676-7

Notice to Readers Food and Drug Administration Approval of an Acellular Pertussis Vaccine for the Initial Four Doses of the Diphtheria, Tetanus, and Pertussis Vaccination Series

The Advisory Committee on Immunization Practices (ACIP) and the Committee on Infectious Diseases, American Academy of Pediatrics, recommend that children routinely receive a series of five doses of vaccine against diphtheria, tetanus, and pertussis before age 7 years (1,2). On July 31, 1996, the Food and Drug Administration licensed Connaught Laboratories, Inc.* (Swiftwater, Pennsylvania), to distribute a combined diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) (Tripedia {Registered}**), for the initial four doses of the diphtheria, tetanus, and pertussis vaccination series. Vaccine doses should be administered at ages 2 months, 4 months, 6 months, and 15-20 months, with an interval of at least 6 months between the third and fourth doses. Available data are insufficient to evaluate the use of Tripedia {Registered} as a fifth dose among children aged 4-6 years who have received Tripedia {Registered} for the previous four doses. Additional information about the immunogenicity and safety of a fifth dose following four previous doses of the same acellular vaccine is being collected and should be

available before infants started on this new schedule are aged 4-6 years and require a fifth dose.

Tripedia {Registered} is the first acellular pertussis vaccine to be licensed in the United States for the first three doses of the diphtheria, tetanus, and pertussis vaccination series. Tripedia {Registered} may be used to complete the primary series in infants who have received one or two doses of diphtheria and tetanus toxoids and whole-cell pertussis vaccine (DTP). For children who have received DTP for the first three doses of the series, two acellular pertussis vaccines (Tripedia {Registered} and ACEL-IMUNE {Registered} (Wyeth-Lederle Vaccines and Pediatrics (Pearl River, New York))) already are licensed for the fourth and fifth doses of the series (3,4). The fifth dose of either DTaP or DTP is not necessary if the fourth dose was administered on or after the fourth birthday (1,2).

The following evidence supports use of Tripedia {Registered} for the first four doses of the diphtheria, tetanus, and pertussis vaccination series:

1. The rates of local reactions, fever, and other common systemic symptoms following receipt of Tripedia {Registered} inoculations are lower than those following whole-cell DTP vaccination for each of the first four doses in the series (3,5; Connaught Laboratories, Inc., unpublished data).

2. The protective efficacy of three doses of Tripedia {Registered} against pertussis disease (defined as cough lasting greater than or equal to 21 days with culture confirmation of infection with Bordetella pertussis) when administered at approximately 3, 5, and 7 months of age was

80% (95% confidence interval {CI}=59%-90%) in a case-control study in Germany (Connaught Laboratories, Inc., unpublished data). In a randomized, placebo-controlled clinical trial in Sweden, the acellular component of this vaccine manufactured by BIKEN, Inc., was administered as a two-dose series to children aged 5-14 months (6). Point estimates of protective efficacy were 69% (95% CI=47%-82%) for cases of culture-confirmed pertussis with any cough lasting greater than or equal to 1 day and 79% (95% CI=57%-90%) for cases of culture-confirmed disease of greater than 30 days' duration.

Because of the reduced frequency of adverse reactions and high efficacy, the ACIP recommends DTaP for routine use as the first four doses of the pertussis vaccination series. During the transition period from use of whole-cell DTP to DTaP, vaccines containing a whole-cell pertussis component continue to be an acceptable alternative for all doses in the pertussis vaccination series. A complete statement by the ACIP about recommendations for use of DTaP among infants is being developed.

References

1. ACIP. Diphtheria, tetanus, and pertussis: recommendations for vaccine use and other preventive measures--recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1991;40(no. RR-10).

2. American Academy of Pediatrics. Report of the Committee on Infectious Diseases. Elk Grove Village, Illinois: American Academy of Pediatrics, Committee on Infectious Diseases, 1991.

3. CDC. Pertussis vaccination: acellular pertussis vaccine for the fourth and fifth doses of the DTP series -- update to the supplementary ACIP statement. Recommendations of the Advisory Committee on Immunization Practices. MMWR 1992;41(no. RR-15).

4. CDC. Pertussis vaccination: acellular pertussis vaccine for reinforcing and booster use -- supplementary ACIP statement. Recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1992;41(no. RR-1).

5. Decker MD, Edwards KM, Steinhoff MC, et al. Comparison of 13 acellular pertussis vaccines: adverse reactions. Pediatrics 1995;96(suppl): 557-66.

6. Ad Hoc Group for the Study of Pertussis Vaccines. Placebo-controlled trial of two acellular pertussis vaccines in Sweden -- protective efficacy and adverse events. Lancet 1988;1:955-60.

EXHIBIT 11

CDC

[Graphics Omitted]

MMWR

Weekly

February 7, 1997 / 46(06);110-111

Notice to Readers FDA Approval of a Second Acellular Pertussis Vaccine for Use Among Infants and Young Children

On December 30, 1996, the Food and Drug Administration (FDA) licensed Wyeth-Lederle Vaccines and Pediatrics to distribute a combined diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) (ACEL-IMUNE{Registered}*) ** for all five doses of the diphtheria, tetanus, and pertussis vaccination series administered to infants and children aged 6 weeks-6 years (before the seventh birthday). Since December 1991, ACEL-IMUNE{Registered} has been licensed for use as the fourth and fifth doses of the vaccination series among children aged 15 months-6 years who previously received three or four doses of diphtheria and tetanus toxoids combined with whole-cell pertussis vaccine (DTP). ACEL-IMUNE{Registered} is the second acellular pertussis-containing vaccine to be licensed for use in infants in the United States (1).

The Advisory Committee on Immunization Practices (ACIP); Committee on Infectious Diseases, American Academy of Pediatrics; and American Academy of Family Physicians recommend that children routinely receive a series of five doses of vaccine against diphtheria, tetanus, and pertussis before age 7 years

(2-5). The first four doses should be administered at ages 2, 4, 6, and 15-18 months and the fifth dose at age 4-6 years.

The following evidence supports the use of ACEL-IMUNE {Registered} for the diphtheria, tetanus, and pertussis vaccination series:

1. The rates of local reactions, fever, and other common systemic symptoms following receipt of ACEL-IMUNE{Registered} inoculations were lower than those following whole-cell pertussis vaccination (administered as DTP) for doses one through four in controlled clinical studies. The rates of these reactions following the fifth dose of ACEL-IMUNE{Registered} were no greater than the rates described for historical controls who received a fifth dose of DTP after four previous doses of DTP (6, package insert).

2. Efficacy of ACEL-IMUNE{Registered} was assessed in a prospective study in Erlangen, Germany. Infants were randomly assigned to groups that were administered either ACEL-IMUNE{Registered} or DTP (distributed by Wyeth-Lederle Vaccines and Pediatrics) at mean ages 3, 5, 7, and 17 months. A third group of infants (not selected randomly) received DT at ages 3, 5, and 17 months. In this trial, pertussis was defined as cough illness lasting é21 days with at least one pertussis-associated symptom (paroxysms, whoop, or post-tussive vomiting) confirmed by culture, serology, or epidemiologic link to a culture-positive household contact. The adjusted vaccine efficacy after three doses and before receipt of the fourth dose was 73% (95% confidence interval {CI}=51%-86%) for ACEL-IMUNE{Registered} and 83%

(95% CI=65%-92%) for DTP. The adjusted efficacy after four doses of ACEL-IMUNE {Registered} was 85% (95% CI=76%-90%). Adjusted efficacy of four doses of DTP was 94% (95% CI=89%-97%). Considering all observation time, (i.e., including after the third dose until the fourth dose {approximately 40% of follow-up time} and after the fourth dose until the end of the study {approximately 60% of follow-up time}), the adjusted efficacy estimated for ACEL-IMUNE{Registered} was 81% (95% CI=73%-87%) compared with 91% for DTP (95% CI=85%-95%) (package insert).

Because of the reduced frequency of adverse reactions and high efficacy, the ACIP recommends DTaP (either ACEL-IMUNE{Registered} or Tripedia{Registered} (Connaught Laboratories, Inc., Swiftwater, Pennsylvania)) for all doses of the routine diphtheria, tetanus, and pertussis vaccination series (1). DTaP also is recommended for all remaining doses in the schedule for children who have started the vaccination series with one, two, three, or four doses of DTP. During the transition period from use of whole-cell DTP to DTaP, vaccines containing a whole-cell pertussis component continue to be an acceptable alternative for all doses in the pertussis vaccination series.

Whenever feasible, the same DTaP vaccine should be used throughout the entire vaccination series. No data exist on the safety, immunogenicity, or efficacy of different DTaP vaccines when administered interchangeably in the primary or booster vaccination of a child. However, if the vaccine provider does not know or have available the type of DTaP vaccine the child to be vaccinated had previously received, any of the licensed DTaP vaccines may be used to complete

the vaccination series. ACIP is developing recommendations for use of DTaP among infants.

References

1. CDC. Food and Ding Administration approval of an acellular pertussis vaccine for the initial four doses of the diphtheria, tetanus, and pertussis vaccination series. MMWR 1996;45:676-7.

2. CDC. Diphtheria, tetanus, and pertussis: recommendations for vaccine use and other preventive measures -- recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1991;40(no. RR-10).

3. American Academy of Pediatrics. Pertussis. In: Peter G, ed. 1994 Red book: report of the Committee on Infectious Diseases. 23rd ed. Elk Grove Village, Illinois: American Academy of Pediatrics, Committee on Infectious Diseases, 1994:355-67.

4. CDC. Pertussis vaccination: acellular pertussis vaccine for reinforcing and booster use -- supplementary ACIP statement: recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1992;41(no. RR-1).

5. CDC. Pertussis vaccination: acellular pertussis vaccine for the fourth and fifth doses of the DTP series: update to the supplementary ACIP statement: recommendations of the Advisory Committee on Immunization Practices. MMWR 1992;41(no. RR-15).

6. Decker MD, Edwards KM, Steinhoff MC, et al. Comparison of 13 acellular pertussis vaccines: adverse reactions. Pediatrics 1995;96(suppl): 557-66.

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

[Filed Mar. 7, 2007]

PLAINTIFFS' FIRST AMENDED COMPLAINT AND JURY DEMAND

Plaintiffs Russell Bruesewitz and Robalee Bruesewitz, individually and as Next Friend to Hannah Bruesewitz, file this Complaint against Defendant, WYETH, f/k/a WYETH LABORATORIES, WYETH-AYERST, WYETH-AYERST LABORATORIES, WYETH LEDERLE, LEDERLE LABORATORIES, a Delaware corporation ("Wyeth"), for injuries sustained by Hannah Bruesewitz as the result of Defendant's DPT vaccination.

The Parties

Plaintiffs

1. Plaintiff Hannah Bruesewitz is a minor and a resident of Allegheny County, Pennsylvania. She is a citizen of the State of Pennsylvania.

2. Plaintiff Russell Bruesewitz is *sui juris*, the father and natural guardian of the minor Plaintiff Hannah Bruesewitz, and a resident of Allegheny County, Pennsylvania. He is a citizen of the State of Pennsylvania.

3. Plaintiff Robalee Bruesewitz is *sui juris*, the mother and natural guardian of the minor Plaintiff Hannah Bruesewitz and a resident of Allegheny County, Pennsylvania. She is a citizen of the State of Pennsylvania.

Defendant

4. The Defendant, WYETH, is a Delaware corporation that conducts business throughout the United States, including Pennsylvania. Defendant has been served and has answered and appeared in this matter.

Jurisdiction & Venue

5. This Court has jurisdiction over this lawsuit under 28 U.S.C. § 1332(a)(1) because the Plaintiffs and the Defendant are citizens of different states, and the amount in controversy exceeds $75,000, excluding interest and costs,

6. Venue is proper in this district under 28 U.S.C. § 1391(a)(1) because Defendant Wyeth resides in this district. Wyeth is a domestic corporation in the Commonwealth of Delaware maintaining a place of business in Philadelphia, Pennsylvania.

Factual Allegations Common to All Counts

7. On October 20, 1991, Hannah Bruesewitz was born a normal healthy baby.

8. Hannah Bruesewitz received her first Diphtheria-Pertussis-Tetanus (hereinafter "DPT") vaccination on December 3, 1991 and her second DPT vaccination on February 4, 1992.

9. On April 1, 1992, Hannah Bruesewitz received her third vaccination, Lederle Lot 314-985 with an expiration dated of April 1993.

10. Within hours of receiving her third DPT vaccination, Hannah Bruesewitz had her first seizure.

11. Hannah Bruesewitz was subsequently diagnosed with a residual seizure disorder and a severe neurological injury.

Knowledge

12. The risk of injury from the DPT vaccine outweighs the benefit. One internal document notes:

> In several European countries, the pertussis portion of the vaccine is no longer administered because studies there supposedly show that the risks involved outweigh the danger of contracting whooping cough.

Outline, circa 1983, Bates No. CP378282.

13. Defendant has long had knowledge of problems with its DPT vaccine. As an example, Defendant was aware that Eli Lilly's vaccine was superior:

> We are aware of the fact that one of the three bacterial components present in Lilly Tri-Solgen is probably of a purer nature than our own. The Pertussis Vaccine in Tri-Solgen has received additional processing presumably by a method described in a patent issued to E. Lilly.

> In a limited field study which we carried out some years ago comparing Tri-Solgen to Lederle Tri-Immunol, it was observed that the Lilly product was better tolerated.

Cyanamid Memo dated January 27, 1972 from M. S. Cooper, Bates No. 314549.

14. Another memo described the necessity to improve upon Defendant's vaccine: "I have pointed out in previous correspondence that some room remains for further purification of the Pertussis Vaccine component to a cell-free product such as is now marketed by E. Lilly." Memo dated June 17, 1975 from M. E. Cooper, Bates No. 529226.

15. Another internal document provides one example of what many doctors experienced upon switching from Lilly's Tri-Solgen to Defendant's vaccine:

> In a word – DISASTER. His nurse tells me that every patient that used our product on reacted with very high temperatures — plus the sore arms etc that they were used to with Lillys DPT. As the mothers all complained to her she has no choice but to return to the Lilly product.

Memo dated March 21, 1964 from F. P. Geoghegan, Bates No. 326921.

16. Another document shows that Defendant had knowledge that the incidence rates were much higher than disclosed: "Far from the expected incidence of one in 15,000 immunizations, there have been five out of 1500 or an incidence of one in 300 of generalized seizures." Report dated September 6, 1978 by Marc W. Deitch, M.D.

Problems with Testing

17. Defendant documents also demonstrate its awareness of shortcomings in the toxicity testing of the DPT vaccine before release to the public: "It is obvious that severe neurologic reactions have occurred in children after immunization with pertussis vaccines which have passed the toxicity and potency tests currently in use." Pertussis Vaccine Encephalopathy by C. N. Christensen, M.D., Bates No. D 000287.

18. Another internal document shows knowledge that the toxicity test in mice was defective and had not been correlated to effects of the vaccine in humans: "This mouse test has many defects, among which is the variability of different strains of mice to pertussis vaccine and the fact that there never has been an effort to relate the toxicity test in mice with toxicity of the vaccine in children." Memo dated August 10, 1965 from N. P. Pierman, Quality Control, Bates No. 317752.

19. Yet another memo considers it "imperative" to improve the vaccine's testing: "In order to accomplish this, we consider it imperative to recognize the differences in sensitivity levels for various strains of mice, and we hope the establishment of a reference preparation for the present pertussis toxicity test is not long delayed." Memo – Recent laboratory experience in the U.S.A. with the pertussis toxicity test by H. D. Piersma, F. W. Bingham, A. E. Bolyn, A. H. Brueckner, H. A. Bettwiler, W. W. Frankhouser, D. M. Marshall and C. Newman, Bates No. CP100148.

Costs

20. Despite knowledge that a safer alternative design for the vaccine existed, costs appeared to factor heavily in Defendant's decision to delay introduction

of a safer product: "This market is dominated by Lilly because of the better pertussis component in the product. . . . The effort is not worth it for the total market." Report of Special Committee for Study of the Biological Business dated June 27, 1967 by E. H. Dearborn, J. D. Gallagher, E. J. Scoble, J. W. Skinner, C. R. Wherley, Bates No. CP373051.

Factual Allegations Relating to the National Vaccine Injury Compensation Program

21. On April 3, 1995, Hannah Bruesewitz filed a petition in the National Vaccine Injury Compensation Program ("NVICP") pursuant to the requirements set forth in 42 U.S.C. § 300aa-11.

22. On February 12, 2003, Hannah Bruesewitz elected to reject the judgment entered in the NVICP pursuant to 42 U.S.C. § 300aa-21(a).

23. Hannah Bruesewitz has met all the statutory requirements outlined in the NVICP to file a civil action.

Counts

24. Plaintiffs incorporate herein by reference the allegations contained in the proceeding paragraphs as though fully set forth herein.

25. At all times relevant hereto, Defendant was involved in the manufacture, sale, distribution, and/or marketing of vaccines.

26. At all times herein mentioned, Defendant was engaged in the business of manufacturing, distributing, offering for sale, supplying, selling, marketing, re-branding, manufacturing of others, packaging and advertising pediatric vaccines.

27. At all times herein mentioned, Defendant negligently and carelessly researched, manufactured, designed, tested or failed to test, abated or failed

to abate, warned or failed to warn of the health hazards, distributed, bought, offered for sale, supplied, sold, marketed, re-branded, manufactured for others, packaged, and advertised certain vaccines.

28. The DPT vaccine administered to Hannah Bruesewitz on April 1, 1992 proximately caused personal injuries to Hannah Bruesewitz and her parents, Russell and Robalee Bruesewitz. The vaccine administered to Hannah Bruesewitz was used in a manner that was reasonably foreseeable, thereby rendering said vaccine unsafe and unreasonably dangerous for use by the public at large and for Hannah Bruesewitz.

29. Defendant knew, or should have known, that the DPT vaccine could and would cause serious injury to Hannah Bruesewitz, and that foreseeable use, i.e., the vaccination process, could and would cause significant injury.

30. During all requisite time periods, an alternative safer design for the DPT vaccine was available.

31. Defendant had the duty to exercise due care in the pursuit of the activities mentioned above and Defendant intentionally, recklessly, maliciously, willfully, wantonly, and outrageously breached its duty of due care. Hannah Bruesewitz received damages in the form of personal injuries which were proximately caused by Defendant's breach of duty.

Count 1 — Negligence

32. Wyeth is charged with the duty to act reasonably, given the foreseeable risk of harm to potential users of its vaccines, and in light of then current scientific or medical knowledge. The failure to meet this standard of care constitutes negligence and subjects Wyeth to liability for the resulting conse-

quences. The foreseeability of severe reactions to pertussis vaccination dates back to at least 1933, when the Journal of the American Medical Association published an article on the subject. Byers and Moll published an article in 1948 reporting 15 severe cases of reactions to pertussis vaccination (two died and seven became mentally retarded). Internal documents from Defendant and some package inserts demonstrate actual awareness in the 1950s of the work of Byers and Moll. Additional internal documents demonstrate Defendant's continuing awareness of severe adverse reactions through April 1, 1992, the date Hannah Bruesewitz received her seizure inducing vaccination.

33. Awareness of the risks of whole cell pertussis vaccines led many, including Defendant, to invesigate safer alternatives. As one example, a method for making a soluble pertussis vaccine was developed by Pillemer and published in Lancet in 1954. Defendant's internal documents demonstrate Defendant's actual awareness in 1958 of the Pillemer method. Another example would be Eli Lilly Co., which submitted a license application for Tri-Solgen in 1959. Information from a three-year clinical investigation demonstrating Tri-Solgen's reduced reaction rate and increased antibody response was submitted with the application.

34. Yet another method was developed by Dr. Barta at Connaught Laboratories and published in the journal Immunology in 1963. Sata, Arai, and Suzuki developed another well-recognized method of making acellular pertussis vaccine in the early 1970's. Defendant was aware, or should have been aware, of these and other safer alternatives to its whole cell pertussis vaccine. Defendant actually purchased the

rights to Tri-Solgen from Eli Lilly Co. in 1976 but never produced it. Instead of pursuing development and licensing of an alternative to TRI-IMMUNOL, Defendant raised the prices to cover liability. Defendant's internal documents show it had the ability to make acellular pertussis vaccine but repeatedly chose not to for many years because of a belief that higher production costs would impair profitability. Plaintiffs contend that Defendant's decision to continue selling whole cell pertussis vaccine rather than pursue a safer alternative design constitutes negligence. By the time Defendant did bring an acellular pertussis vaccine to market, it was too late for Hannah Bruesewitz.

Count 2 — Negligence (Failure to Warn)

35. The package inserts included by Defendant with its vaccine over the years of production provided progressively increased detail regarding the incidence and severity of adverse reactions. Plaintiffs have not yet been able to identify the particular package insert to the vaccine dose that triggered Hannah Bruesewitz's injuries. Nevertheless, Plaintiffs contend the evidence will show that Defendant either knew or should have known of the actual incidence of adverse reactions was higher, and that Defendant under-reported the incidence of adverse reactions in the relevant package insert. In particular, Defendant's manufacturing process and inadequate quality control resulted in recurrent problems with maintaining the appropriate balance between neuron-toxins and endo-toxins in the pertussis vaccine. Such batches were known in the vernacular of the trade as "Hot Lots." The manufacturing defect problem was sufficiently well recognized that the Centers for Disease Control (CDC) promulgated an

official definition of "Hot Lot." The CDC defined a "Hot Lot" as one that generates at least ten reports of the illness or two reports of seizure or two reports of deaths. Thirty-three adverse events, including one death, were reported from the same vaccine lot before Hannah Bruesewitz was vaccinated on April 1, 1992. In addition, Defendant affirmatively tried to hide the actual incidence of adverse reactions by changing its disbursement process to prevent the discovery of "Hot Lots" and misrepresenting to doctors the reactivity of its vaccine relative to Tri-Solgen. One internal document describes attempts to try to hide such "Hot Lots": "After the reporting of the SID [Death] cases in Tennessee, we discussed the merits of limiting distribution of a large number of vials from a single lot to a single state, county or city health department and obtained agreement from the senior management staff to proceed with such a plan."

Memo dated August 27, 1979 from Alan Berstein, Wyeth. 1992.

Defendant was negligent in failing to remove, recall, or warn of problems with the lot and the DPT vaccine in general before Hannah Bruesewitz was vaccinated.

Count 3 — Strict Liability (Design Defect)

36. In contrast to Plaintiffs' negligence based claims, strict liability focuses on Defendant's product rather than Defendant's conduct. Specifically, the TRI-IMMUNOL vaccine sold by Defendant and administered to Hannah Bruesewitz was in a defective condition and unreasonably dangerous to the user. Defendant acknowledges that local adverse reactions included pain, erythema, tenderness and induration at the site of injection. Significant reactions included

high fever, a transient shock-like episode, excessive screaming (three or more hours), somnolence, convulsions, encephalopathy and thrombocytopenia. Encephalopathy can lead to permanent brain damage or death. The existence or feasibility of safer alternative designs is evidence that Defendant's vaccine was defective and unreasonably dangerous when administered to Hannah Bruesewitz. The existence and feasibility of better, safer alternatives to TRI-IMMUNOL is demonstrated by Defendant's internal documents, the actual production of such alternatives by others, the eventual development and approval in 1991 of Defendant's ACEL-IMUNE for the four and/or fifth shots in the five-shot series, and approval of ACEL-IMUNE for all five doses of the recommended DPT vaccination series in December 1996.

Count 4 — Strict Liability (Manufacturing Defect)

37. Although Plaintiffs contend that Defendant's pertussis vaccine was unreasonably dangerous when manufactured as designed, Plaintiffs further contend that the specific dose given to Hannah Bruesewitz contained a manufacturing defect that made it extra-hazardous. Defendant's manufacturing process and inadequate quality control resulted in recurrent problems with maintaining the appropriate balance between neuron-toxins and endo-toxins in the pertussis vaccine. Such batches, as noted earlier, were known in the vernacular of the trade as "Hot Lots," which the CDC defines as one that generates at least ten reports of the illness or two reports of seizure or two reports of deaths. The lot from which Hannah Bruesewitz was vaccinated met this definition prior to her receiving it and ultimately triggered a total of

66 adverse event reports, and caused two deaths. Because the reporting system is passive, the actual number of adverse events for any given "Hot Lot" is believed to be higher. Plaintiffs contend the vaccination administered to Hannah Bruesewitz came from a defective or "Hot Lot."

Prayer for Relief

ACCORDINGLY, the Plaintiffs demand judgment against the Defendant as follows:

38. Recovery of damages to Hannah Bruesewitz in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial; and

39. An award of prejudgment and post-judgment interest, and cost of suit, as provided by law;

40. Punitive damages, in an amount to be determined at trial; and

41. Such other legal and equitable relief as this Court deems just and proper.

Respectfully submitted,

/s/ John R. Fabry

John R. Fabry, Esquire
Fed ID No. 24525
WILLIAMS BAILEY LAW FIRM, LLP
8441 Gulf Freeway, Suite 600
Houston, Texas 77017
Phone: (713) 230-2284
Fax: (713) 643-6226

Robert E. J. Curran
Fed. ID No. 08620
CURRAN & BYRNE
P.O. Box 30
Media, PA 19063
Phone: (610) 565-0505
Fax: (610) 565-7315

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

[Filed Mar. 19, 2007]

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR LEAVE TO AMEND

[TEXT OMITTED]

EXHIBIT A

Donald H. Marks, M.D., Ph.D.
Internal Medicine and Microbiology

9340 Helena Road, Suite F-414
Hoover, Alabama 35244

phone: 1-205-682-7389
fax: 1-603-372-4813
e-mail: DHMarks@yahoo.com

February 8, 2007

John Fabry, Esq.
Williams Bailey Law Firm
8441 Gulf Freeway, Suite 600
Houston, TX 77017-5051

Dear Mr. Fabry:

Thank you for the opportunity to prepare a report concerning the neurologic vaccine reaction to WC-DTP of **Hannah Bruesewitz**. To review my qualifications, I am a diplomat of the American Board of Internal Medicine, licensed to practice medicine in three states and actively practicing medicine, and am a Fellow of the American College of Physicians. I also have significant clinical and bench top research training, utilizing the scientific methods, and hold a separate doctorate in Microbiology.

I have over 20 years of experience in pharmaceutical medicine, and am a member of the American Association of Pharmaceutical Physicians and Regulatory Affairs Professional Society. I was the former Associate Director for Clinical Research, Antibacterials at Hoffman LaRoche Pharmaceuticals, and the Director for Clinical Research at Connaught Pasteur Merieux

Vaccines. The procedures I use in determining whether a causal relationship exists between a drug, biological or vaccine and an adverse effect is the same scientific methodology utilized by the FDA and US pharmaceutical companies. This is based upon accepted rules of scientific evidence, and using algorithms as described by Hill and Ridell. I employ these very techniques when assessing adverse events in clinical research in which I am involved, and on behalf of clients for the defense and for plaintiffs. In general, I fail to find a causal relationship in more than 80% of the cases I review. I am qualified to review this case and render an opinion, and am familiar with the standards of practice relating to drug-induced adverse events.

Diphtheria, tetanus and pertussis (DTP) are infectious diseases caused by bacteria, which have a significant effect on the health of children. For many years, vaccines against the causative organisms have been available. The two major issues of vaccinology are the efficacy of the vaccine, and the vaccine's safety. These issues are often linked, and it is quite possible and desired for a vaccine to be both safe and effective. For the case of the first DTP vaccines, efficacy was demonstrated, but there were reports of significant safety issues early on (Madsen 1933). Because vaccines try to induce a neutralizing reaction to the infecting organism, in the beginning vaccinologists used whole bacterial cells as the immunizing agent. These were either attenuated (weakened) bacterial strains, or simply crude mixtures of whole bacteria, produced by lysis or disruption of the cell.

Severe neurologic and other adverse effects (AE) from DTP vaccine have for many years been attributed to the pertussis component. Because of the

severe neurologic and other effects which could occur from vaccination with whole cell vaccines (such as Tri-Immunol, Wyeth Lederle), attempts were made to inactivate the vaccines, and hopefully the offending components, with formalin and other chemicals. When simple chemical inactivation of the vaccine proved unsuccessful in abating severe neurologic AE, chromatography was used to filter the crude vaccine components (Pillemer 1954). It was observed early on that the pertussis components of fractionated vaccines were both immunogenic (Felton and Verwey in 1953 and 1955), protective, and had a much smoother adverse effect profile (less reactigenic). This led to the early development of acellular (component, fractionated) pertussis vaccines in the 1930s (Lederle, patent in 1937), with soluable pertussis toxin (Joslin 1939).

Manufacturers of WC-DTP were aware early on of the adverse effect profile of their vaccine approach (Madsen 1933; Byers 1948), compared to aDTP. Such AEs included local reactions such as pain, erythema, tenderness and induration at the site of injection. Significant systemic reactions included high fever, a transient shock-like episode, excessive screaming, somnolence, convulsions, encephalopathy, and thrombocytopenia. Encephalopathy can lead to permanent brain damage or death. Byers and Moll published an article in 1948 reporting 15 severe cases of reactions to pertussis vaccination (two died and seven became mentally retarded).

The better safety profile of acellular (cell wall membrane removed) vaccine was attributed to the removal of crude bacterial cell wall fractions, which are known to activate many pathways in humans for inflammation, allergic and other toxic reactions.

Interestingly, specific pertussis components (FHA, pertactin, and fimbriae) which were fractionated could even be mixed back in to a vaccine if there were concerns about adequate immunogenicity and efficacy. The fractionation approach was so appealing that Lilly began producing Tri-Solgen in 1962, a combined DTP vaccine which used a soluble pertussis component, indicating that the acellular approach to pertussis component was safe, effective, and commercially viable. By the late 1960's, when I was an undergraduate in college, the knowledge and application of column chromatography and protein chemistry were widely known and well-advanced, and being taught to biology and pre-med students.

Because the licensing application for the Tri-Solgen was filed in 1959, the clinical studies supporting efficacy and safety would have had to have been run in the years 1955 thru 1958. Soon (1966) after Tri-Solgen was marketed, a number of other vaccine manufacturers (for ex Merck, PD) changed from WC-DTP to aDTP. Over the ensuing years, debates still took place over whether the WC-DTP vaccine was more immunogenic than aDTP, which could have been equated to efficacy. Only marginal differences in efficacy were ever demonstrated, and few studies were conducted. The limitation on studies was that at that time surrogate markers of efficacy were not known, so only large scale epidemiologic studies could take place, and these were both costly and took many years to complete. Because both vaccines were efficacious, the main motivation for running head-to-head studies of WC-DTP v aDTP was more commercial, and the cost of the studies was not offset by the profit margins and expected benefits in terms

of marketing and improved sales and capture of increasing percentages of markets.

Clinical trials (in house by Lederle) were run in 1968, comparing the acellular vaccine (Tri-Solgen) made by Lilly with the whole cell vaccine (Tri-Immunol) made by Lederle, and clearly showed that the acellular vaccine was far less toxic. By the early 1980's the clinical results of the acellular Japanese vaccine (Sato 1984) had also demonstrated that the acellular vaccine was equivalent to the whole cell vaccine.

Eventually, manufacturers of WC-DTP such as Lederle (TRI-IMMUNOL, produced since 1949) changed over to aDTP (ACEL-IMUNE). In the case of ACEL-IMUNE, the eventual development and approval in 1991 of ACEL-IMUNE was initially only for the fourth and/or fifth shots in the five shot series, but in 1996 approval was finally given for all five doses of DTP. Had Lederle made an ethical business decision to change completely from WC DTP to aDTP once there were significant safety concerns raised and a reasonably effective alternative (aDTP) available, they could have completed their changeover sooner, and not even had WC-DTP available at the time Hannah took her 3rd dose. Lederle could also have advised prescribers and parents that aDTP was safer than WC-DTP, at any point in the vaccine schedule. Instead of simply discontinuing the more reactogenic WC-DTP (TRI-IMMUNOL), Lederle continued for strictly economic reasons to market both vaccines. Because of this, Hannah B received her injections of TRI-IMMUNOL in April 1, 1992, and this immediately triggered the predictable, not unexpected severe neurologic adverse effects which caused the effects which persist to this day.

It is known in the vaccine industry that there is some variation in production lots of vaccines, with some lots being more reactogenic than others. Individual vaccine manufactures maintain internal lists of "hot lots," (at least ten reported adverse events and/or two reported seizure cases and/or two reported deaths; NVIC) production lots which had higher than expected reports of adverse reactions. The lot from which Hannah Bruesewitz was vaccinated triggered a total of 66 adverse event reports, including two deaths, and certainly would have been indicated as a Hot Lot. By not making this specific information available to medical personnel administering this vaccine, to the patents of vaccines, or recalling that vaccine lot, the labeling was inadequate.

Conclusions: I can say with a reasonable degree of medical certainty that:

1) It should have been well-known to Lederle and to the vaccine industry as a whole, for many years that acellular DTP was a safer alternative to whole cell DTP, and therefore WC-DTP was unreasonably dangerous in light of the potential for severe neurologic adverse effects,

2) The manufacturer was capable of switching from WC DTP to aDTP for many years before Hannah was given her immunization, but failed to do so, and this was not a reasonable and responsible action for a vaccine manufacturer to take,

3) Failing to recall this "hot lot" was not a reasonable and responsible action for a vaccine manufacturer to take,

4) The WC-DTP vaccine was causally related to the seizures and subsequent neurologic deterioration of Hannah B.

5) Had Hannah B received aDTP instead of WC DTP, it is more likely than not that she would not have had this reaction and subsequent severe persistent neurologic damage.

My opinions are based on:

- the temporal relatedness of the adverse neurologic events to vaccination,
- the known pharmacology and adverse event profile of DTP vaccines,
- the mechanism of action as elucidated from articles in the medical literature on neurologic adverse events occurring as a result of WC and acellular vaccines (some are listed at the end of this report),
- the medical literature on the subject (cited below),
- my experience as a vaccine industry safety officer and a clinical researcher,
- my ongoing experience in vaccine clinical research,
- my experience and training both in as an internal medicine physician, and as a doctorate in Microbiology,
- my experience as a practicing hospital-based internal medicine physician,
- and the lack of a more likely alternative explanation.

All of the foregoing opinions are held to a reasonable degree of medical certainty. I reserve the right to

modify my opinions as additional information becomes available to me.

Thank you for the opportunity to participate in this case. Call me if you have any questions.

Sincerely,

Donald H. Marks, M.D., Ph.D.
Licensed: NY, AL, MS
Fellow, American College of Physicians
Academy of Pharmaceutical Physicians and Investigators
Regulatory Affairs Professional Society

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

[Filed Apr. 2, 2007]

DEFENDANT WYETH, INC.'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

[TEXT OMITTED]

EXHIBIT 3

Frequently Asked Questions About VAERS

- What is VAERS?
- Who can report to VAERS?
- Who should I report to VAERS?
- How do I report to VAERS?
- What events should I report to VAERS?
- How are VAERS reports analyzed?
- Are all events reported to VAERS caused by vaccinations?
- What if I can't tell if a reaction was caused by a vaccine or another medication?
- How do I find out if a vaccine adverse event has been reported to VAERS?
- How can I get information on VAERS?
- Is VAERS involved in the Vaccine Injury Compensation Program?
- Does VAERS provide general vaccine information?

What is VAERS?

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. Since 1990, VAERS has received over 123,000 reports, most of which describe mild side effects such as fever. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS helps to

identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

Who can report to VAERS?

Anyone can report to VAERS. The majority of VAERS reports are sent in by vaccine manufacturers (42%) and health care providers (30%). The remaining reports are obtained from state immunization programs (12%), vaccine recipients (or their parent/guardians, 7%) and other sources (9%). Vaccine recipients or their parents or guardians are encouraged to seek the help of their health care professional in filling out the VAERS form.

Why should I report to VAERS?

Each report provides valuable information that is added to the VAERS database. Accurate and complete reporting of post-vaccination events supplies the information needed for evaluation of vaccine safety. The CDC and FDA use VAERS information to ensure the safest strategies of vaccine use and to further reduce the rare risks associated with vaccines.

How do I report to VAERS?

You should use a VAERS report form to report any adverse event. You can obtain pre-addressed postage paid report forms by calling VAERS at 1-800-822-7957. You may use photocopies of the form to submit reports. You may also download printable copies of the VAERS form as well as other information about the VAERS Program from the following Internet sites:

- The VAERS Web site at http://vaers.hhs.gov/
- The Food and Drug Administration's Web site at http://www.fda.gov/char/vaers/vaers.htm

- The Centers for Disease Control and Prevention Web site at http://www.cdc.gov/nip/

What events should I report to VAERS?

VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. You should report clinically significant adverse events even if you are unsure whether a vaccine caused the event.

The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.
- Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination.

A copy of the Reportable Events Table can be obtained by calling VAERS at 1-800-822-7967 or by downloading it from http://vaers.hhs.gov/pubs.htm.

How are VAERS report analyzed?

Both the CDC and the FDA review data reported to VAERS. The FDA reviews reports to assess whether a reported event is adequately reflected in product labeling, and closely monitors reporting trends for individual vaccine lots. Copies of published reviews are available from VAERS. Many different types of events occur after vaccination. Approximately 85% of the reports describe mild events such as fever, local reactions, episodes of crying or mild irritability, and other less serious experiences. The remaining 15% of the reports reflect serious adverse events involving life-threatening conditions, hospitalization,

permanent disability, or death, which may or may not have been truly caused by an immunization.

Are all events reported to VAERS caused by vaccinations?

No. VAERS receives reports of many events that occur after immunization. Some of these events may occur coincidentally following vaccination, while others may truly be caused by vaccination. Studies help determine if there is more than a temporal (time) association between immunization and adverse events. The fact that an adverse event occurred following immunization is not conclusive evidence that the event was caused by a vaccine. Factors such as medical history and other medications given near the time of the vaccination must be examined to determine if they could have caused the adverse event. It is important to remember that many adverse events reported to VAERS may not be caused by vaccines.

What if I can't tell if a reaction was caused by a vaccine or another medication?

We encourage you to report any reaction following vaccination to VAERS, regardless of whether or not you can tell if the vaccine or another product caused it. Reports sent to the VAERS program that also make reference to non-vaccine pharmaceutical products are shared with MedWatch, the FDA's drug safety surveillance system.

How do I find out if a vaccine adverse event has been reported to VAERS?

You can request information about adverse events reported to VAERS by faxing requests to (301) 443-1726, or by sending requests to:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857
(301) 827-6500

How can I get information on VAERS?

There are four ways to obtain information about the VAERS program:

- Send e-mail inquiries to info@vaers.org
- Visit the VAERS Web site at: http://vaers.hhs.gov
- Call the toll-free VAERS information line at (800) 822-7967
- Fax inquiries to the toll-free information fax line at (877) 721-0366

Is VAERS involved in the Vaccine Injury Compensation Program?

No. The National Childhood Vaccine Injury Act created the Vaccine Injury Compensation Program (VICP) to compensate individuals whose injuries may have been caused by vaccines recommended by the CDC for routine use. VICP is separate from the VAERS program. Reporting an event to VAERS does not file a claim for compensation to the VICP.

A petition must be filed with VICP to start a claim for compensation. For more information call (800) 338-2382, or go to http://www.hrsa.gov/vaccinecompensation/default.htm.

Does VAERS provide general vaccine information?

No. VAERS concentrates on collecting and analyzing the report data. For general information about vaccines and vaccine safety, immunization schedules

for children and adults, publications on vaccine-preventable diseases, and more:

- Call the CDC National Immunization Hotline at:
  - o (800) 232-2522 (English)
  - o (800) 232-0233 (Spanish)
- Visit CDC's National Immunization Program Web site at http://www.cdc.gov/nip/.

VAERS Mailing Address:

VAERS
P.O. Box 1100
Rockville, MD 20849-1100

EXHIBIT 4

CDC

[Graphics omitted]

Vaccine "Hot Lots"

Question:

I've heard there are "hot lots" of vaccines that have been associated with more adverse events and deaths than others and that parents should find the numbers of these lots and not allow their children to receive vaccines from them.

Answer:

This misconception got considerable publicity recently when vaccine safety was the subject of a television news program. First of all, the concept of a "hot lot" of vaccine as it is used in this context is wrong. It is based on the presumption that the more reports to VAERS** a vaccine lot is associated with, the more dangerous the vaccine in that lot; and that by consulting a list of the number of reports per lot, a parent can identify vaccine lots to avoid.

This is misleading for two reasons:

1. VAERS is a system for reporting events that are *temporally associated* with receipt of vaccine; VAERS reports should not be interpreted to imply causality. In other words, a VAERS report does not mean that the vaccine caused the event. Statistically, a certain number of serious illnesses, even deaths, can be expected to occur by chance alone among children recently vaccinated. Although vaccines are known to cause minor, temporary side effects such as soreness

or fever, there is little, if any, evidence linking vaccination with permanent health problems or death. The point is that just because an adverse event has been reported to VAERS does not mean it was caused by a vaccine.

2. Vaccine lots are not the same. The sizes of vaccine lots might vary from several hundred thousand doses to several million, and some are in distribution much longer than others. Naturally a larger lot or one that is in distribution longer will be associated with more adverse events, simply by chance. Also, more coincidental deaths are associated with vaccines given in infancy than later in childhood, since the background death rates for children are highest during the first year of life. So knowing that lot A has been associated with x number of adverse events while lot B has been associated with y number would not necessarily say anything about the relative safety of the two lots, even if the vaccine *did* cause the events.

Reviewing published list of "hot lots" will not help parents identify the best or worst vaccines for their children. If the number and type of VAERS reports for a particular vaccine lot suggested that it was associated with more serious adverse events or deaths than are expected by chance, the Food and Drug Administration (FDA) has the legal authority to immediately recall that lot. To date, no vaccine lot in the modern era has been found to be unsafe on the basis of VAERS reports.

All vaccine manufacturing facilities and vaccine products are licensed by the FDA. In addition, every vaccine lot is safety-tested by the manufacturer. The results of these tests are reviewed by FDA, who may

repeat some of these tests as an additional protective measure. FDA also inspects vaccine-manufacturing facilities regularly to ensure adherence to manufacturing procedures and product-testing regulations, and reviews the weekly VAERS reports for each lot searching for unusual patterns. FDA would recall a lot of vaccine at the first sign of problems. There is no benefit to either the FDA or the manufacturer in allowing unsafe vaccine to remain on the market. The American public would not tolerate vaccines if they did not have to conform to the most rigorous safety standards. The mere fact is that a vaccine lot still in distribution says that the FDA considers it safe.

DECLARATION OF MARY B. RITCHEY

I, Mary B. Ritchey, declare and state as follows:

1. I received a Ph.D. in Microbiology from Cornell University in 1975. In 1977, I joined American Cyanamid Company ("Cyanamid"), which among other things, manufactured the diphtheria, tetanus, and whole-cell pertussis ("DTP") vaccine (trade name TRI-IMMUNOL®). Cyanamid was acquired by American Home Products Corporation ("AHPC") in November 1994, and, in March 2002, AHPC changed its name to Wyeth. I retired from Wyeth in 2006, at which time I was the Vice President of Vaccine Research and Development Quality Assurance at Wyeth. A true and correct copy of my curriculum vitae, which sets forth my educational background and my employment history with Cyanamid and AHPC, is attached hereto as Exhibit A.

2. I make this declaration to address what I understand to be an allegation made by plaintiffs about an alleged manufacturing defect or problem in a lot of TRI-IMMUNOL®. I have been informed by counsel for Wyeth that the lot at issue was manufactured by Cyanamid in 1991 and was the source of the vaccine administered to the minor plaintiff on April 1, 1992. I am further informed by counsel that the specific allegation advanced by plaintiffs is that, "Defendant's manufacturing process and inadequate quality control resulted in recurrent problems with maintaining an appropriate balance between neurotoxins and endo-toxins in the pertussis vaccine."

3. I am fully familiar with the manufacturing and quality control processes in effect in 1991, as I then held the position of Senior Director of Quality Control at Cyanamid, which was responsible for

the quality control of among other things, the TRI-IMMUNOL® vaccine.

4. Plaintiffs' allegation that Cyanamid's "manufacturing process and inadequate quality control resulted in recurrent problems with maintaining an appropriate balance between neuro-toxins and endo-toxins in the pertussis vaccine" does not make any sense, as it does not reflect any aspect of the manufacturing and quality control processes applicable to the preparation of TRI-IMMUNOL®. More specifically, although I do not understand what actual components of the vaccine plaintiffs refer to as purported "neuro-toxins," I do understand what is referred to as "endo-toxins," and I know that the preparation of TRI-IMMUNOL® did not involve the use of any particular standard amount or specified range of endotoxins (as endotoxins are intrinsic to the whole pertussis cell), much less a "balance" between endotoxins and any other component of the pertussis cell. Thus, because Cyanamid never sought to "maintain[]" an appropriate balance between neuro-toxins and endo-toxins in the pertussis vaccine," it follows that Cyanamid never experienced any "problems" of the type alleged by plaintiffs.

5. As detailed in paragraphs 27-36 below, I have reviewed the quality control records from what I have been informed is the lot at issue, and I have confirmed that the lot passed all required testing, including potency and toxicity testing of the pertussis vaccine.

TRI-IMMUNOL® BACKGROUND

6. TRI-IMMUNOL® is a combination of three immunizing agents: tetanus toxoid, diphtheria toxoid, and whole-cell pertussis vaccine, adsorbed. TRI-IMMUNOL® was used in the routine immunization

of children in this country against the deadly diseases of diphtheria, tetanus ("lockjaw") and pertussis ("whooping cough").

7. Whole-cell pertussis vaccines consist of a suspension of whole, killed pertussis cells which provoke an antibody response that provides immunity. The killed pertussis organism is non-infective and cannot produce the natural disease. The whole Bordetella pertussis bacterium was used to ensure that all the parts of the cell necessary to stimulate an immune response and, thus confer immunity against whooping cough, were present in the vaccine.

8. Endotoxins are an integral part of the cell wall structure of a gram negative bacterium, such as pertussis, and thus are always included in a whole-cell pertussis vaccine. The amount of endotoxins found in any individual Bordetella pertussis bacterium is a product of nature. Some variation in the endotoxins in lots of whole-cell DTP vaccine is inevitable because the Bordetella pertussis cells used in such vaccines are biological organisms with inherent variability.

9. The pertussis bacterium does not contain a recognized "neuro-toxin" component. Indeed, I do not understand what part of the pertussis vaccine plaintiffs refer to when they allege that "neurotoxins" were not balanced with endotoxins in TRI-IMMUNOL®. While for many years there was a debate in the scientific community as to whether whole-cell pertussis vaccine could have a neuro-toxic effect, there is certainly no constituent part of the pertussis cell that is known or referred to as a "neuro-toxin." To my knowledge it has never been proven that whole-cell pertussis vaccine has a neuro-toxic effect.

TRI-IMMUNOL®'S DESIGN

10. It is my understanding that Cyanamid first received FDA approval to distribute its DTP vaccine, TRI-IMMUNOL®, in the mid-1940s.

11. In April 1992, when I understand that the minor plaintiff received the DTP vaccine at issue in this action, the childhood vaccination schedule recommended by the Advisory Committee on Immunization Practices ("ACIP") of the federal government's Centers for Disease Control and Prevention ("CDC"), included the administration of FDA-approved DTP vaccine at approximately 2, 4, 6, and 15-18 months, and 4-6 years of age. In April 1992, whole cell was the only type of pertussis vaccine licensed by the FDA for use in 2, 4 and 6 month old infants (which I have been informed was the minor plaintiff's age group at the time), although toddlers could receive either whole cell or acellular DTP vaccine if they had already received three doses of whole-cell DTP. "Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures Recommendations of the Immunization Practices Advisory Committee (ACIP)," dated August 1, 1991, is attached hereto as Exhibit B. "Pertussis Vaccination: Acellular Pertussis Vaccine for Reinforcing and Booster Use – Supplementary ACIP Statement Recommendations of the Immunization Practices Advisory Committee," dated February 7, 1992, is attached hereto as Exhibit C.

12. The design and manufacturing process of TRI-IMMUNOL® was at all times regulated by the FDA.

13. TRI-IMMUNOL®'s product license application details the procedure used to manufacture TRI-IMMUNOL®, including (i) the method of growing the organism for inoculation; (ii) the preparation of the

tetanus toxin, diphtheria toxin, and pertussis component; (iii) the methods of detoxification; (iv) the method of purification of the diphtheria and tetanus toxoids; and (v) the preparation and testing of the final product. A detailed description of the design and manufacturing requirements for TRI-IMMUNOL® is set forth in the Application and Report on Manufacture of Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed dated June 30, 1981, is attached hereto as Exhibit D.

14. Endotoxins are an integral part of the cell wall, and the whole-cell pertussis component could not be made without endotoxins. Thus, endotoxins were inherently part of the whole-cell pertussis vaccine design.

15. The pertussis component of TRI-IMMUNOL® could not fail to meet the intended product specifications by virtue of having too many or too few endotoxins because neither the FDA-approved design of TRI-IMMUNOL®, nor any FDA regulation, set a standard for the amount of endotoxins in the vaccine.

16. The FDA-approved design of the pertussis component of TRI-IMMUNOL® did not identify or specify any standard amount of any component identified as "neuro-toxins."

17. No part of TRI-IMMUNOL®'s product design and manufacturing specifications required Cyanamid to balance or adjust endotoxins with "neuro-toxins," or with any other component of the vaccine.

TESTING OF TRI-IMMUNOL®

18. The FDA extensively regulated the testing and release of every lot of TRI-IMMUNOL®. Each lot of TRI-IMMUNOL® is tested to verify whether it meets

its own design specifications and other FDA standards.

19. In 1991, FDA regulations required that each lot of TRI-IMMUNOL® vaccine undergo safety testing (21 C.F.R. §§ 610.11, 620.6 (1991)), sterility testing (21 C.F.R. § 610.12 (1991)), purity testing (21 C.F.R. § 610.13 (1991)), and identity testing (21 C.F.R. § 610.14 (1991)). FDA regulations also required that pertussis vaccine be tested for potency and toxicity using a specific mouse potency test (21 C.F.R. § 620.4 (1991)) and mouse toxicity test (21 C.F.R. § 620.5 (1991)). Attached herto as Exhibit E is a true and correct copy of the relevant FDA regulations in effect during 1991.

20. Safety testing includes injecting mice with TRI-IMMUNOL® to determine whether every lot of vaccine fell within the acceptable range for potency and toxicity as defined by the FDA.

21. The potency test requires that mice by vaccinated with TRI-IMMUNOL® and then subjected to live, disease causing bacteria to verify that the vaccine generates antigens to confer immunity against the disease. For this test, a specified number of healthy mice are injected with pertussis vaccine and subsequently challenged intracerebrally with a culture of Bordetella pertussis. Following injection, the mice are observed for 14 days, and the number of mice that died after 72 hours must be recorded. See Ex. E (21 C.F.R. § 620.4). Based on the measured antibody response, the vaccine sample was required to have a potency of at least 12 units per total human immunizing dose. See id.

22. The mouse toxicity test requires a group of no less than 10 mice, with each mouse weighing 14 to 16 grams. After determining the group weight of the

mice, each mouse is injected intraperitoneally with a test dose of one-half of the largest recommended single human dose of the final vaccine. The group weight of the mice is then determined at the end of 72 hours, and at the end of 7 days after injection. The lot passes the toxicity test if: i) after 72 hours, the average weight per mouse is no less than the average weight per mouse immediately preceeding the injection; ii) after 7 days, the average weight gain per mouse is no less than 3.0 grams; and (iii) after 7 days there are no more than 5 percent of vaccine-related deaths out of the total number of mice in all the toxicity tests performed. See Ex. E (21 C.F.R. § 620.5).

23. The mouse toxicity test is a means by which to evaluate the toxicity of the vaccine in its entirety, including all parts of the pertussis bacterium. This test does not measure the specific amount of any component in the pertussis bacterium, but rather measures the effect that the vaccine has when administered to a mouse pursuant to an animal model incorporated into the Code of Federal Regulations.

24. The FDA did not require Cyanamid to perform any tests on TRI-IMMUNOL® to determine if there was a balance between different types of toxins, and Cyanamid did not undertake any such tests.

25. In 1991, before the FDA would release a lot of vaccine for distribution to health care providers, the FDA required manufacturers of DTP vaccines to submit to the FDA: (i) samples of each lot of vaccine and (ii) protocols summarizing the manufacturing process and demonstrating that the results of toxicity and potency testing for each lot conformed with federal regulations. See Ex. E (21 C.F.R. § 620.6(h) (1991)).

26. A lot of TRI-IMMUNOL® could not be released for distribution in the United States unless the lot obtained FDA approval for release showing that the lot characteristics met all FDA regulations.

LOT-SPECIFIC QUALITY CONTROL TESTING

27. Cyanamid implemented extensive quality control measures to make certain each lot of TRI-IMMUNOL® vaccine complied in all respects with FDA-approved design, manufacturing, and testing requirements.

28. I am informed by counsel that the TRI-IMMUNOL® vaccine administered to minor plaintiff on April 1, 1992 bore package lot number 314-958. Package lot number 314-958 was a subset of a bulk lot (or manufacturing lot) of TRI-IMMUNOL® bearing the number "1948-0731."

29. I have reviewed the quality control records for bulk lot 1948-0731, and I have confirmed that lot 1948-0731 passed all required testing, including potency and toxicity testing of the pertussis vaccine. A true and correct copy of the quality control records for Tri-IMMUNOL® bulk lot 1948-0731 is attached hereto as Exhibit F.

30. Lot 1948-0731 was tested for pertussis potency using the mouse potency test. See Ex. F at WBRSW011569. The test required that the vaccine have a pertussis potency of at least 12 units per total immunizing dose based upon a single test estimate of not less than 8 units. See id. The test sample passed with a result of 12.49. See id.

31. Lot 1948-0731 was also tested using the required mouse toxicity test. See Ex. F at WBRSW011571-575. At the end of 72 hours, the average weight per mouse was no less than the aver-

age weight per mouse preceding injection with the test vaccine. See id. at WBRSW011571. At the end of 7 days, the average gain per mouse was no less than 3.0 grams. Indeed, the lot passed with a result of 5.38 grams. See id. at WBRSW011572. Of the 20 mice tested, no mouse died during the toxicity test (although the test allows for a vaccine-related death rate of 5%). See id.

32. Lot 1948-0731 passed the safety test (Ex. F at WBRSW011575) and the sterility test (Ex. F at WBRSW011576). Lot 1948-0731 also passed the tests calculating the amounts of thimerosal, formaldehyde, aluminum, and methanol in the test sample. See Ex. F at WBRSW001157576-578.

33. The amount of bacterial endotoxins in Lot 1948-0731 was measured purely for data collection purposes. There was no standard against which endotoxins for the pertussis vaccine component were evaluated. See Ex. F at WBRSW0011581-582. This measurement did not constitute a test, was not required by the FDA, and the resulting data had no part in the evaluation of the lot as acceptable for release.

34. As noted in the Manufacturing Summary of Final Product for Lot 1948-0731, "[a]ll tests in this protocol pass." See Ex. F at WBRSW0011585.

35. As required, samples of TRI-IMMUNOL® bulk lot 1948-0731 were submitted to the FDA's Center for Biologics Evaluation and Research for testing along with protocols summarizing the manufacturing processes and setting forth the results of toxicity and potency testing. See Ex. F at WBRSW011664.

36. On June 5, 1991, the FDA approved the release of TRI-IMMUNOL® bulk lot 1948-0731. See Ex. F at WBRSW011584.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in Norwood, New Jersey this 2nd day of April, 2007.

/s/ MARY B. RITCHEY
Mary B. Ritchey, Ph.D.

EXHIBIT C

CDC

[Graphics Omitted]

MMWR

Recommendations and Reports

February 7, 1992 / 41(RR-1);1-10

Pertussis Vaccination: Acellular Pertussis Vaccine for Reinforcing and Booster Use – Supplementary ACIP Statement Recommendations of the Immunization Practices Advisory Committee

U.S. Department of Health and Human Services Public Health Service Centers for Disease Control National Center for Prevention Services Division of Immunization Atlanta, Georgia 30333

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Centers for Disease Control William L. Roper, MD., M.P.H., Director

The recommendations on pertussis were developed by the Immunization Practices Advisory Committee (ACIP), in collaboration with:

National Center for Prevention Services Alan R. Hinman, M.D., M.P.H., Director Division of Immunization Walter A. Orenstein, M.D., Director Vaccine Safety Activity Steven G. F. Wassilak, M.D., Chief

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Epidemiology Program Office Stephen B. Thacker, M.D., M.Sc., Director Richard A. Goodman, M.D., M.P.H., Editor MMWR Series

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This supplementary statement provides information on and recommendations for the use of diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). One such vaccine was recently licensed, ACEL-IMUNE.* This vaccine is licensed for use only as the fourth and fifth doses of diphtheria, tetanus, and pertussis vaccination; it is not licensed for the initial three-dose series in infants and children, regardless of age. At least one other DTaP product is anticipated to be licensed in the future for use as fourth and fifth doses. The current Immunization Practices Advisory Committee (ACIP) statement on diphtheria, tetanus, and pertussis issued August 8, 1991, gives general recommendations on pertussis prevention, including the use of whole-cell pertussis vaccines for primary and booster vaccination (1).

INTRODUCTION

Current Whole-Cell Pertussis Vaccines

Simultaneous vaccination against diphtheria, tetanus, and pertussis during infancy and childhood has been a routine practice in the United States since the late 1940s. Whole-cell pertussis vaccines in the United States have been and continue to be prepared from suspensions of inactivated or disrupted Bordetella pertussis whole bacterial cells. Routine vacci-

nation with whole-cell pertussis vaccines has been highly effective in reducing the burden of disease and deaths due to pertussis (3). Although the efficacy of each whole-cell vaccine in use in the United States has not been precisely estimated, clear evidence of overall high efficacy is available (4,5).

Whole-cell pertussis vaccines, although safe, are associated with a variety of adverse events, particularly local erythema, swelling and tenderness, fever, and other mild systemic events such as drowsiness, fretfulness, and anorexia (6,7). Infrequently, febrile convulsions and hypotonic-hyporesponsive episodes can occur after whole-cell DTP vaccination (6). The general concerns about safety have led investigators to attempt to develop safer pertusis vaccines that have high efficacy.

Acellular Pertussis Vaccines

General Information

Efforts have been under way for greater than or equal to 20 years to identify and purify the antigens of B. pertussis that can be incorporated into acellular pertussis vaccines that are protective, yet are less likely to induce reactions. In Japan, the initial impetus for the accelerated development of acellular pertussis vaccines was the occurrence in 1975 of two deaths in infants within 24 hours of DTP vaccination (8,9). These events led health authorities to temporarily suspend the routine use of whole-cell DTP vaccine in infants (then initiated at 3 months of age). Routine whole-cell DTP vaccination was rapidly reintroduced in most areas but recommended for administration at age greater than or equal to 2 years. However, vaccination coverage of children decreased, and the incidence of reported pertussis

increased markedly, reaching a peak in 1979. Meanwhile, efforts to purify antigens of B. pertussis were accelerated. After limited clinical studies of immunogenicity and safety, several DTaP vaccines were licensed in Japan in 1981.

Since 1981, methods of purifying the antigenic components of B. pertussis have continued to improve, additional information on the protection of various antigens in animal models has accumulated, and candidate vaccines have been developed by many multinational manufacturers. Current candidate vaccines contain one or more of the bacterial components thought to provide protection. These components include filamentous hemagglutinin (FHA), pertussis toxin (PT -- also known as lymphocytosis promoting-factor, which is inactivated to a toxoid when included in a vaccine), a recently identified 69-kilodalton outer-membrane protein (pertactin; Pn), and agglutinogens of at least two types (fimbriae (Fim) types 2 and 3). Several studies, relating to the immunogenicity and the safety of various candidate acellular pertussis vaccines, are currently being conducted or have been completed among children in the United States and other countries. In general, these vaccines, which are immunogenic, are less likely to cause common adverse reactions than the current whole-cell preparations (10-19).

The efficacy of two acellular pertussis vaccines developed by the Japanese National Institute of Health (JNIH) was studied during the period 1985 through 1987 in a randomized, placebo-controlled clinical trial in Sweden, a county in which pertussis vaccine had not been used routinely since 1979 (20). One vaccine (known in the trial as JNIH-6) contained 23.4 ug/dose each of pertussis toxoid and FHA.

Another vaccine (JNIH-7), not similar to any vaccine used in Japan, contained only 37.7 ug/dose of pertussis toxoid. The 3,801 children who participated in this trial were randomly selected to receive two doses of an acellular pertussis vaccine (approximately 1,420 children in each vaccine group) or a placebo (954 children). Neither of the vaccines nor the placebo contained diphtheria and tetanus toxoids. The first dose of vaccine or placebo was administered to children 5-11 months of age; the second dose was administered 8-12 weeks later. Each vaccine demonstrated some degree of efficacy. For culture-confirmed disease with cough of any duration, the observed efficacy was 69% for JNIH-6 (95% confidence interval (CI), 47%-82%) and 54% for JNIH-7 (95% CI, 26%-72%) (20). Levels of estimated efficacy were higher against culture-confirmed pertussis that was more severe and classic. The efficacy of JNIH-6 was 79% (95% CI, 57%-90%) and that of JNIH-7 was 80% (95% CI, 59%-91%) against culture-confirmed pertussis with cough lasting more than 30 days. However, direct comparisons with whole-cell pertussis vaccine were not available to determine whether one or both of these acellular vaccines conferred protection at least equivalent to that of whole-cell vaccine. This trial also demonstrated that the complexities of evaluating pertussis vaccine efficacy had changed substantially depending upon the case definition used (21-23). Specific serologic correlates of immunity were not identified in this study. It remains undetermined which vaccine components are most effective in inducing protection and which types of immune responses are most responsible for protection. During the trial, four participants died of invasive bacterial disease that occurred up to 5 months after vaccination. Three had received the

JNIH-6 vaccine and one had received JNIH-7 vaccine; the significance of these findings is uncertain (24). Primarily because of concerns regarding the level of efficacy of the following vaccination, neither is licensed for use in Sweden (25).

Until now acellular pertussis vaccines have been licensed for use only in Japan, where, since 1981, such vaccines have been administered routinely to children greater than or equal to 2 years or age (9). Studies of persons exposed to pertussis in household settings have demonstrated the effectiveness of several acellular pertussis vaccines manufactured in Japan in preventing clinical pertussis among children greater than or equal to 2 years of age (8, 26-28). In Japan, with the continued use of acellular pertussis vaccines, the incidence of disease and death caused by pertussis has declined steadily. However, the reported incidence among children age less than 2 years has remained higher than the incidence among children of that age when whole-cell vaccines were routinely used in infants (9). Since 1989, vaccination of infants with Dtap beginning at 3 months of age has been initiated in many areas of Japan at the recommendation of the Ministry of Health. However, the extent of use among children less than 2 years of age remains low (S. Isomura, personal communication, 1991). Therefore, it is too soon to make conclusions about the effect of this policy on the age-specific incidence of pertussis among children less than 2 years of age.

Based on the experiences in Sweden and Japan, questions remain whether acellular pertussis vaccines confer clinical protection when administered early in infancy, or whether protection induced at any age is equivalent to that of whole-cell pertussis

vaccine preparations. Consistent with the licensure of Dtap, the Committee recommends that whole-cell pertussis vaccine be continued for the initial three-dose vaccination series until an alternative vaccine is available that has demonstrated essentially equivalent or higher efficacy. To evaluate the relative protective efficacy of primary vaccination among infants, several clinical trials, which will compare Dtap vaccine with whole-cell DTP vaccine, are in progress or development.

ACEL-IMUNE Information

On December 17, 1991, the FDA licensed one Dtap vaccine for use as the fourth and fifth doses of the recommended DTP series. ACEL-IMUNE contains 40 mcg of protein; approximately 86% of this protein is FHA; 8%, PT; 4%, Pn; and 2%, Fim type 2. The acellular pertussis vaccine component is purified by ammonium sulfate fractionation and sucrose density gradient centrifugation; PT is detoxified by treatment with formaldehyde. Each dose of ACEL-IMUNE contains 7.5 limit of flocculation (Lf) of diphtheria toxoid, 5.0 Lf of tetanus toxoid, and 300 hemagglutinating (HA) units of acellular pertussis vaccine. The FHA and PT components both exhibit HA activity. The combined components are adsorbed to aluminum hydroxide and aluminum phosphate and preserved with 1:10,000 thimerosal.

Household exposure studies have demonstrated efficacy of acellular pertussis vaccines among children in Japan vaccinated at age greater than or equal to 2 years with the Takeda acellular pertussis vaccine component, combined with Takeda-produced diphtheria and tetanus toxoids (27-29). Clinical studies are in progress to examine the relative efficacy of

ACEL-IMUNE in preventing disease when administered to infants at ages 2, 4, and 6 months compared with whole-cell DTP vaccine. The following evidence supports the use of ACEL-IMUNE after the initial infant three-dose series of whole-cell DTP vaccine.

Immunogenicity.

When ACEL-IMUNE is used for the fourth and fifth doses of the vaccination series, antibody responses after administration are generaly similar to those following whole-cell DTP vaccine for the PT, Pn, and Fim components; antibody responses are higher for FHA (Table 1) (17,18).

Clinical efficacy.

In Japan, Takeda-manufactured Dtap vaccine has been shown to prevent pertussis disease among children age greater than or equal to 2 years, however, in this retrospective study clinicians and investigators were not blinded to the vaccination status of the participants (28). The occurrence of pertussis was compared in 62 children vaccinated with two to four doses of Takeda DTaP on or after the second birthday and 62 unvaccinated children for the period 7-30 days after household exposure to pertussis. Typical clinical pertussis occurred in one vaccinated child and 43 unvaccinated children; estimated clinical vaccine efficacy: 98% (95% CI, 84%-99%). Minor respiratory illness – possibly representing mild, atypical pertussis – occurred among an additional eight vaccinated and four unvaccinated children. When these children were included, the estimated vaccine efficacy was 81% (95% CI, 64%-90%). None of the vaccinated household contacts in this study were age less than 2 years; by restricting the analysis of results to household contacts who were age greater

than or equal to 2 years, the corresponding estimates of efficacy were 97% (95% CI, 82%-99%) and 79% (95% CI, 60%-89%) respectively. In a smaller study of similar design, results were similar (29).

Safety.

Local reactions, fever, and other common systemic events occur less frequently after receipt of ACEL-IMUNE vaccinations than after whole-cell DTP vaccination. In general, local and common systemic events occur approximately one-fourth to two-thirds the frequency after whole-cell DTP vaccination (Table 2) (17,18). Available data indicate comparable safety for ACEL-IMUNE and Takeda DTaP packaged in Japan.

VACCINE USAGE

See the general ACIP statement on diphtheria, tetanus, and pertussis for more details (1). This vaccine is licensed only for use as the fourth and fifth doses of the DTP series among children ages 15 months through 6 years of age (before the seventh birthday). Use of DTaP is not recommended for children who have received less than three doses of whole-cell DTP, regardless of age. The Committee considers the first four DTP doses as primary immunization against diphtheria, tetanus, and pertussis. The fourth (reinforcing) dose of DTP, generally given at age 15-18 months, is administered to maintain adequate pertussis immunity during the preschool years. The fifth (booster) dose of DTP is administered at ages 4-6 years of age to confer continued protection against exposure during the early years of school.

Either whole-cell DTP or DTaP can be used interchangeably for the fourth and fifth doses of the rou-

tine series of vaccination against diphtheria, tetanus, and pertussis among children greater than or equal to 15 months of age. The Committee recommends the use of DTaP, if readily available, because it substantially reduces local reactions, fever, and other common systemic events that often follow receipt of whole-cell DTP.

The standard, single-dose volume of ACEL-IMUNE is 0.5 mL and should be administered intramuscularly (IM).

Indications for the Fourth (Reinforcing} Dose

Six to 12 months after the third dose of DTP

One dose of DTaP (instead of whole-cell DTP) can be administered IM to children age 15-18 months (or later when necessary); this dose should be administered at least 6 months after the third dose of whole-cell DTP (Table 3). The fourth dose of either DTaP or DTP is an integral part of the primary immunizing course of pertussis vaccination. DTaP is not licensed for use among children age less than 15 months. Although immunogenicity data among children age 15-16 months are not yet available for ACEL-IMUNE, the Committee suggests that ACEL-IMUNE be used for children as part of the recommended schedule of routine simultaneous vaccination with DTP, oral poliovirus (OPV), and measles-mumps-rubella (MMR) at age 15-18 months (30).

Booster Vaccination

Children 4-6 years of age (up to the seventh birthday)

A dose of DTaP can be administered as the fifth dose in the series for children ages 4-6 years who either have received all four prior doses as whole-cell vac-

cine or for those children who have received three doses of whole-cell DTP and one dose of DTaP. A fifth dose of either DTaP or DTP should be administered before the child enters kindergarten or elementary school. The Committee recommends the use DTaP, if readily available. This fifth dose is not necessary if the fourth dose in the series is given on or after the fourth birthday.

Special Considerations

Vaccination of infants and young children who have a personal or family history of seizures

Recent data suggest that infants and young children who have had previous seizures (whether febrile or nonfebrile) or who have immediate family members with such histories are at increased risk of seizures following DTP vaccination than those without such histories (1). Because these reactions may be due to the fever induced try whole-cell DTP vaccine and because DTaP is infrequently associated with moderate to high fever, use of DTaP is strongly recommended for the fourth and fifth doses if pertussis vaccination is considered for these children (see Precautions and Contraindications). A family history of seizures or other central nervous disorders does not justify withholding pertussis vaccination. Acetaminophen should be given at the time of DTP or DTaP vaccination and every 4 hours for 24 hours to reduce the possibility of postvaccination fever in these children.

Children with a contraindication to pertussis vaccination (see Precautions and Contraindications)

For children younger than age 7 years who have a contraindication to whole-cell pertussis vaccine, DT should be used instead of DTP; DTaP should not be substituted. If additional doses of pertussis vaccine

become contraindicated after a DTP series is begun in the first year of life, DT should be substituted for each remaining scheduled DTP dose.

Pertussis vaccination for persons age greater than or equal to 7 years

Adolescents and adults who have waning immunity are a major reservoir for transmission of pertussis (31). It is possible that booster doses of other preparations of acellular pertussis vaccines will be recommended in the future for persons age greater than or equal to 7 years, although it is not currently recommended.

SIDE EFFECTS AND ADVERSE REACTIONS

For a complete discussion, see the general ACIP statement on diphtheria, tetanus, and pertussis (1).

Although mild systemic reactions such as fever, drowsiness, fretfulness, and anorexia occur frequently after both whole-cell DTP vaccination and ACEL-IMUNE vaccination, they are less common after ACEL-IMUNE vaccination (Table 2). These reactions are self-limited and can be safely managed with symptomatic treatment.

Moderate-to-severe systemic events, including fever greater than or equal to 40.5 C (105 F); persistent, inconsolable crying lasting 3 hours or more; and collapse (hypotonic-hyporesponsive episode) have been rarely reported after vaccination with DTaP (16, 20, 32). Each of these events appears to occur less often than with whole-cell DTP. When these events occur after the administration of whole-cell DTP, they appear to be without sequelae; the limited experience with DTaP suggests a similar outcome.

In U.S, studies, more severe neurologic events, such as prolonged convulsions or encephalopathy, have not been reported in temporal association after administration of approximately 6,500 doses of ACEL-IMUNE. This somewhat limited experience does not allow conclusions to be drawn whether any rare serious adverse events will occur after administration of DTaP. Because DTaP causes fever less frequently than whole-cell DTP, it is anticipated that events such as febrile convulsions will be less common after receiving DTaP.

SIMULTANEOUS ADMINISTRATION OF VACCINES

The simultaneous administration of DTaP, OPV, and MMR has not been evaluated. However, on the basis of studies using whole-cell DTP, the Committee does not anticipate any differences in seroconversion rates and rates of side effects from those observed when the vaccines are administered separately. Although combinations have not been thoroughly studied, simultaneous vaccination with DTaP, MMR, OPV, or inactivated poliovirus vaccine (IPV), and Haemophilus b conjugate vaccine (HbCV) is acceptable; similarly, simultaneous vaccination with DTaP, hepatitis B vaccine (HBV), OPV, IPV, and HbCV is also acceptable. The Committee recommends the simultaneous administration of all vaccines appropriate to the age and the previous vaccination status of the child (30), including the special circumstance of simultaneous administration of DTP or DTaP, OPV, HbCV, and MMR at age greater than or equal to 15 months.

PRECAUTIONS AND CONTRAINDICATIONS

General Considerations

DTaP is licensed only for reinforcing and booster immunization – the fourth and fifth doses in the DTP series. DTaP is not licensed for use among children age less than 15 months, on or after the seventh birthday, or for the initial three-dose series among infants and children regardless of their age.

Contraindications

Because no data currently exist to suggest otherwise, contraindications to further doses of DTaP are the same as those for the whole-cell DTP. If any of the following events occurs in temporal relation with the administration of DTP or DTaP, subsequent vaccination with DTP or DTaP is contraindicated:

1. An immediate anaphylactic reaction.
2. Encephalopathy (not due to another identifiable cause), defined as an acute, severe central nervous system disorder occurring within 7 days after vaccination and generally consisting of major alterations consciousness, unresponsiveness, or generalized or focal seizures that persist more than a few hours, without recovery within 24 hours.

Precautions (Warnings)

If any of the following events occurs in temporal relation with the receipt of either whole-cell DTP or DTaP, the decision to administer subsequent doses of vaccine containing the pertussis component should be carefully considered. Although these events were once considered absolute contraindications to whole-cell DTP, there may be circumstances, such as a high

incidence of pertussis, in which the potential benefits outweigh the possible risks, particularly since the following events have not been proven to cause permanent sequelae:

1. Temperature of greater than or equal to 40.5 C (105 F) within 48 hours, not due to another identifiable cause.
2. Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours.
3. Persistent, inconsolable crying lasting greater than or equal to 3 hours, occuring within 48 hours.
4. Convulsions with or without fever, occurring within 3 days.

If these events occur after receipt of any of the first four doses of whole-cell DTP vaccine and if additional doses of pertussis vaccine are indicated because the potential benefits outweigh the potential risks, consideration should be given to the use of DTaP for the fourth and fifth doses.

REPORTING OF ADVERSE EVENTS AFTER VACCINATION

As with any newly licensed vaccine, surveillance for information regarding the safety of DTaP in large-scale use is important. Surveillance information aids in the assessment of vaccine safety, although its usefulness is limited, by identifying potential events that may warrant further study. Additionally, specific evaluations of DTaP use in larger populations than those studied for license application are being initiated.

The Vaccine Adverse Event Reporting System (VAERS) of the Department of Health and Human Services became operational in November, 1990. VAERS is designed to accept reports of all serious adverse events that occur after receipt of DTaP, as well as any other vaccine, including but not limited to those mandated by the National Childhood Vaccine Injury Act of 1986 (33). Any questions about reporting requirements, completion of the report form, or requests for reporting forms can be directed to 1-800-822-7967.

- Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed is prepared and distributed as ACEL-IMUNE by Lederle Laboratories (Pearl River, New York) and was licensed December 17, 1991 (2). The acellular pertussis vaccine component is produced by Takeda Chemical Industries, Ltd. (Osaka, Japan), and is combined with diphtheria and tetanus toxoids manufactured by Lederle Laboratories.

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Table 1

Note: To print large tables and graphs users may have to change their printer settings to landscape and use a small font size.

Table 1. Comparison of immunologic responses to pertussis antigens among children vaccinated with ACEL-IMUNE(R) and among children vaccinated with whole-cell DTP given as the fourth DTP dose at 17-24 months of age and as the fifth DTP dose at 4-6 years of age*

	% with >=4-fold increase 30 days after vaccination at 17-24 months of age		% with >=4-fold increase 30 days after vaccination at 4-6 years of age	
Assay	ACEL-IMUNE(R)	Whole-Cell DTP	ACEL-IMUNE(R)	Whole-Cell DTP
Pertussis toxin +	94 (N=36) &	74 (N=35)	84 (N=38)	88 (N=40)
Filamentous Hemagglutinin	92 (N=36) &	60 (N=35)	97 (N=38)	85 (N=40)
Pertactin +	81 (N=16)	89 (N=18)	86 (N=36)	68 (N=34)
Agglutination	82 (N=34)	86 (N=35)	47 (N=32) &	72 (N=36)

* Among children previously vaccinated with whole-cell DTP, the number of specimens tested differ by assay. From Morgan CM, Blumberg DA, Cherry JD, et al., (17) and Blumberg DA, Mink CM, Cherry JD, et al., (18).

\+ By enzyme immunoassay.

& $P<0.05$.

Table 2

Note: To print large tables and graphs users may have to change their printer settings to landscape and use a small font size.

Table 2. Comparison of frequency (%) of adverse events occurring within 72 hours after vaccination with ACEL-IMUNE(R) or whole-cell DTP among children given the fourth DTP dose at 17-24 months of age and the fifth DTP dose at 4-6 years of age *

Events	ACEL-IMUNE(R) N=911 +	Whole-Cell DTP N=178 +
Local		
Any erythema	29 &	50
Erythema>2 cm	10 &	21
Any induration	25 &	40
Induration>2 cm	7 &	12
Pain/tenderness	26 &	73
Systemic		
Fever >= 38 C (100.4 F)	19 &	26
Fever >= 39 C (102.2 F)	1.5	1.7
Antipyretic use	6 &	17
Drowsiness	6 &	22
Fretfulness	17 &	33
Vomiting	2 &	8

* Among children previously vaccinated with whole-cell DTP; from Morgan CM, Blumberg DA, Cherry JD, et al, (17) and Blumberg DA, Mink CM, Cherry JD, et al, (18) and manufacturer's unpublished data.

\+ Of the 911 doses of ACEL-IMUNE(R), 778 were given as the fourth dose and 133 were given as the fifth dose; of the 178 doses of whole-cell DTP, the numbers were 89 and 89, respectively.

& $P<0.05$

Table 3

Note: To print large tables and graphs users may have to change their printer settings to landscape and use a small font size.

Table 3. Routine diphtheria, tetanus, and pertussis vaccination schedule summary for children >7 years of age – United States, 1992

Dose	Age	Customary age/interval	Product
Primary 1	2 months	>= 6 weeks of age	DTP *
Primary 2	4 months	4-8 weeks after first dose +	DTP *
Primary 3	6 months	4-8 weeks after second dose +	DTP *
Primary 4	15 months	6-12 months after third dose +	DTaP or DTP *&
Booster	Age 4-6 years, before entering kindergarten or elementary school (not necessary if fourth primary vaccinating dose administered after fourth birthday)		DTaP or DTP *&
Additional boosters	Every 10 years after last dose		Td @

* Use DT if pertussis vaccine is contraindicated. If the child is age >=1 year at the time that primary dose three is due, a third dose 6-12 months after the second dose is administered completes primary vaccination with DT.

\+ Prolonging the interval does not require restarting series.

& Either DTaP or whole-cell DTP can be used for the fourth and fifth doses; DTaP is generally preferred, if available.

@ Tetanus-diphtheria toxoids absorbed (Td) (for adult use).

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

[Filed May 8, 2007]

ANSWER AND AFFIRMATIVE DEFENSES OF WYETH, INC. TO PLAINTIFFS' FIRST AMENDED COMPLAINT AND JURY DEMAND

Defendant Wyeth, Inc. ("Wyeth"), improperly named as "Wyeth, Inc., f/k/a Wyeth Laboratories, Wyeth-Ayerst Laboratories, Wyeth Lederle Vaccines, and Lederle Laboratories," hereby responds to the allegations in Plaintiffs' First Amended Complaint and Jury Demand ("Amended Complaint") as follows:

* * * * *

9. Wyeth admits that medical records produced by plaintiffs in the course of discovery conducted in connection with this action reflect that Hannah

Bruesewitz received a DTP vaccination on April 1, 1992. Wyeth further admits that a record of Hannah Bruesewitz's "Immunization and Skin Testing" bears the notation "314 958 Lederle."

10. Wyeth admits that medical records produced by plaintiffs in the course of discovery conducted in connection with this action reflect that Hannah Bruesewitz received a DTP vaccination on April 1, 1992. Wyeth further admits that medical records produced by plaintiffs in this action reflect that Hannah Bruesewitz experienced a seizure on April 1, 1992. Except as so admitted, Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the Amended. Complaint.

* * * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

[Filed May 18, 2007]

DEFENDANT WYETH, INC.'S THIRD MOTION FOR SUMMARY JUDGMENT PURSUANT TO FED. R. CIV. P. 56(b)

[TEXT OMITTED]

EXHIBIT C

Children's Hospital of Pittsburgh
Division of Child Neurology
One Children's Place
3705 Fifth Avenue
Pittsburgh, PA 15213-3147

Michael J. Painter, M.D.
Patricia K. Crumrins, M.D.
Henry B. Wessel, M.D.
Ira Bergman, M.D.
Mark S. Scher,, M.D.
Nina F. Schor, M.D., Ph.D.
Vinodh Narayanan, M.D.
Rajiv Varma, M.D.

Phone:
(day) 412/692-5520
(night) 412/692-5325

NEUROLOGY CLINIC

CASE REPORT: 4/21/92

Name: BRUSEWITZ, HANNAH
Born: 10/20/91
Unit: 65-80-89

Hannah is seen in the Neurology clinic today with her mother for follow-up evaluation after her recent admission to Children's Hospital for new onset of seizures.

Since discharge on 4/16, Hannah has had three seizures, two were on the 16th and one was on the 19th. The seizures were all brief, less than 30 seconds and consisting of head tremor and staring. There were no changes in her respiratory patterns or her color.

Over the past five days, Hannah has run intermittent low grade fevers of 101°. She is slightly less active than usual and has had mild URI symptoms. Also, currently mother and father both have upper respiratory infections. Hannah remains playful, eating well.

MEDICATIONS: She is on no other medications except the Tegretol at a dose of 80-60-60 and phenobarbital 10 mg., q.a.m.

NEUROLOGICAL EXAM: Hannah is an alert, attentive and playful infact. She is very attentive to her surroundings and to the examiner.

Pupils are equal and reactive. Extraocular movements are intact. Face is symmetric to movement and to sensation.

Motor Exam: Active and passive tones are normal. Reflexes are 2+ and symmetrical. Babinski signs are equivocal.

Sensory Exam: She withdrew quickly to light touch and to pinch.

Coordination: She could reach for a small cube with a raking grasp. She demonstrated good midline skills and she had a good parachute reflex.

IMPRESSION: Hannah's seizures are under reasonable control at this time. The etiology of her epilepsy is still unknown.

PLAN: Today we will check a Tegretol level as well as a CBC and liver enzymes. We will see her again in one week. Based on her Tegretol level today, we may increase her dose. We will wean her phenobarbital to 5 mg., q.a.m. over the next three days and then discontinue it.

ADDENDUM: Her Tegretol level was 9.2. We will keep her on the current dosage regimen.

/s/ MICHAEL J. PAINTER

Michael J. Painter, M.D., Chief
Division of Child Neurology

MJP/dm

Dictated by: Harry Abram, M.D.

cc: Jane Breck, M.D.
3471 Fifth Avenue
#1110
Pittsburgh, PA 15213

EXHIBIT D

[Logo Omitted]
Children's
Hospital of Pittsburgh

3705 Fifth Avenue
Pittsburgh, PA 15213

CHILD DEVELOPMENT UNIT DEVELOPMENTAL
NEUROBEHAVIORAL EVALUATION

BRUESEWITZ, HANNAH
MRN 65089
DOB 10/20/1991
DOS 12/04/2003
CA 12 years

REASON FOR EVALUATION

Hannah was seen at the Child Development Unit recently for an assessment of her current developmental and behavioral status, a review of her progress, and an assessment of her need for ongoing mental health and educational services. The evaluation is being conducted to determine the medical necessity of comprehensive Wrap-Around Services, along with other intervention needs.

RELEVANT BACKGROUND INFORMATION

Strengths: Hannah is typically a pleasant girl who enjoys sensory activities and particularly enjoys her experiences at school with typical children. Her family continues to be extremely supportive and to advocate very effectively for her needs. Her family feels that her receptive language has improved to some extent. She will follow familiar directions in the appropriate social context, such as "put your

clothes in the chute," and "go get your backpack, it is time to go."

Concerns: Hannah continues to demonstrate resistance to adult directions. She has actually demonstrated some increase in the frequency of these episodes. She will plop down on the floor when she is urged to make a transition in her activity. This happens both at home and at school. Both Hannah's family and the individuals involved in providing therapy for her feel that, about half of the time, these episodes occur because Hannah does not understand what is coming next and, when she does understand, the transition is much easier. A substantial component of the resistance, however, is felt to be related to noncompliance. Another concern is the family's ongoing feeling that the school is inconsistent in its ability to deal effectively with Hannah's resistance and a lack of optimal communication between the family and the school.

MEDICAL AND DEVELOPMENTAL HISTORY

The background information is unchanged from previous evaluations. Hannah has been quite stable from the standpoint of her seizure disorder. She continues on Keppra and Felbatol. It has been recommended by Hannah's pediatrician, Dr. Breck, that Hannah be seen by an endocrinologist to consider hormonal treatment to manage her menstrual periods. I certainly support this recommendation. In addition, Dr. Breck has suggested that Hannah be seen by Dr. Antonio Harden, a child psychologist at Western Psychiatric Institute, who may be able to prescribe medication for what is seen as Hannah's impulsivity. Dr. Harden is an outstanding child psychiatrist, and I support this recommendation as well. Hannah is due to see Dr. Crumrine, a pediatric neu-

rologist, in the near future. Hannah occasionally has episodes of laugher that do not seem to be appropriate for the social context, and there is some concern that this might represent seizure activity. There was one episode of self-injurious behavior in which Hannah ripped her fingernail off. This episode occurred around the time of her menses, and there is a question about whether this behavior is related to discomfort.

EDUCATIONAL AND INTERVENTION HISTORY

Hannah is currently in an autistic support classroom in the Mount Lebanon School District and is mainstreamed for a number of activities that she enjoys very much. The family continues to have some concerns about the adequacy of services that are being provided through the School and have a meeting very shortly at the School District regarding special education services. She is scheduled to enter middle school next year, and the family is very concerned about the appropriate classroom placement for her. They are considering a life-skills classroom in the Mount Lebanon School District, along with a number of special education placements. Among these options include the Pathfinder School, D. T. Watson, the Wesley Institute, and the Tillotson School, which I would support the family's considering as well. The family will be doing some investigating this spring and will make a plan for transition to middle school. She is due to be evaluated educationally this spring on that this information can contribute to placement decisions.

INVOLVEMENT IN OTHER COMMUNITY/ SOCIAL SETTINGS

Hannah continues to be involved in a play group through Presley-Ridge. Her Wrap-Around Services are

being provided by the Sharp Visions program. She continues to receive occupational therapy services with sensory stimulation.

CURRENT DEVELOPMENTAL AND BEHAVIORAL CONCERNS

Hannah's most significant needs continue to be communication skills and her need for sensory stimulation. The family is working actively with the Sharp Visions staff to address her resistance. She continues to need a great deal of support in order to be involved in appropriate community and peer group activities, although she has continued to have some successes in this regard.

DIAGNOSTIC FORMULATION

Axis I	Pervasive developmental disorder, not otherwise specified
Axis II	Cognitive delay
Axis III	Seizure disorder
Axis IV	Moderate psychological stressors
Axis V	GAV-40

SUMMARY AND DISCUSSION

Hannah is a 12-year-old girl with pervasive developmental disorder and seizure disorder that has been under good control lately. She continues to require intensive high-quality one-on-one intervention in order to develop functional communication and social interaction. She did make some progress over the summer in a very intensive program, and there is some concern about whether this rate of progress will be maintained in her current school placement. Hannah continues to require on-on-one intervention through the Sharp Visions program.

RECOMMENDATIONS

1. Hannah should continue to receive comprehensive Wrap-Around Services through the Sharp Visions program. Hannah should receive 15 hours per week of therapeutic staff support, 16 hours per month of behavior specialist consultation, and a rehabilitation aide at the rate of 4 hours per week.
2. Hannah should continue to attend the play group at the Presley-Ridge Program.
3. Hannah should continue to receive occupational therapy, speech therapy, and music therapy in the school. Consideration should be given to having specific sensory activities integrated into her classroom.
4. The behavior program should focus on her current needs, including improvement in spontaneous communication and specific behavior management of Hannah's resistance to transitions.
5. Hannah continues to need support for peer group interactions, and this should be provided in the form of an aide in the classroom who can help Hannah during her mainstreaming activities.

I would be happy to see Hannah back in follow-up in four months to re-evaluate her progress and would be more than happy to provide support to the family as they make the decision about appropriate placement in middle school.

Dena Holkosh, MD
Director, Child Development Unit

EXHIBIT F

WYETH
CLINICAL RESEARCH & DEVELOPMENT
DIVISION TRIP REPORT

PRODUCT
D-P-T Vaccine

PROJECT NO.

TRIP DATE
September 6, 1978

PAGE 1 OF 2 PAGES

TRIP SUBJECT Larry J. Baraff, M.D.
Assistant Professor of Pediatrics
Emergency Medical Center
U.C.L.A. Hospital and Clinic
Los Angeles, California 90024

REPORT SUMMARY

I met with Dr. Larry Baraff at the Emergency Medical Center in the U.C.L.A. Hospital complex on Wednesday, September 6, 1978. Dr. Baraff is currently involved in a large scale study of reactogenicity of currently marketed D-P-T vaccine. He has to date administered about 1500 doses, 1200 of which are currently licensed Wyeth D-P-T vaccine. These have been administered in either out-patient clinics, Kaiser-Permanente clinics or private pediatrician's office within the Los Angeles county area. He is evaluating the reactions based on home visits by his nursing staff or questionnaires received from parents of immunized infants. They are looking at such variables as change in cry pattern, change in feeding pattern, fever, irritability, generalized reactions, i.e.,

seizures, and local reactions such as swelling, tenderness and redness.

Far from the expected incidence of one in 15,000 immunizations, there have been five out of 1500 or an incidence of one in 300 of generalized seizures. These have occurred in infants all under six months of age which is below the usual lower limit defined for febrile seizure disorders. There have been two episodes of total "collapse" characterized by unresponsiveness, hypotension, bradycardia, and a shock-like picture occurring within a couple hours after the vaccine has been administered.

In general, Dr. Baraff feels that the reaction rate both local, generalized and systemic for currently marketed D-P-T vaccines containing whole pertussis virus is unacceptable. He claims that his feelings are reinforced by phone calls and letters which he receives constantly from practitioners, clinic directors, and pediatricians in the California area who are equally convinced that the whole virus vaccine is highly reactogenic. Dr. Baraff claims that this is in opposition to prior experience in the pediatric community with the solubilized antigen. He, therefore, is greatly in favor of investigating Wyeth's new formulation containing the solubilized antigen adsorbed with aluminum phosphate. He would be able to perform a 100 patient study very quickly comparing two groups of 50 children each receiving three doses of either the new vaccine or the currently marketed product. Agglutination and inhibition titer testing would be done by Dr. Richard Stiehm, Professor of Pediatrics and Chief of Immunology at U.C.L.A. The bloods would be drawn prior to receiving the first dose and 30 days after receiving the third dose of vaccine. Doses would be given at the recommended

2, 4, and 6 month well baby visits. All patients would be well babies attending the maternal and child health clinics at U.C.L.A. and would be under the care of Dr. Baraff or one of several nurse practitioners during the time of the study. Dr. Baraff is prepared to initiate the study as soon as possible and does not foresee any difficulties in obtaining institutional review of this protocol.

Dr. Baraff will be attending a meeting at the Bureau of Biologics with Dr. Manhclark on Monday, September 11th to present his data and discuss the proposed protocol utilizing Wyeth's new vaccine. He will contact me on arriving back in Los Angeles

PREPARED BY
Marc W. Deitch, M.D.

DATE:
9/15/78

APPROVED BY: ORIGINAL RETAINED
Barry R. Walker, M.D.

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Dr. A. Bernstein
Dr. F McCarthy

DECLARATION OF DENNIS J. FOLEY, PH.D.

I, Dennis J. Foley, Ph.D., declare and state as follows:

1. I am the former Vice President, World Wide Regulatory Affairs – Vaccines, for Wyeth Research, a business unit of Wyeth (formerly known as American Home Products Corporation), in Pearl River, New York. I retired from my employment with Wyeth in 2005. I submit this declaration in support of Defendant Wyeth's Third Motion for Summary Judgment. Specifically, I make this declaration to show that Wyeth complied in all material respects with the statutory requirements of 21 U.S.C. § 301 et seq., 42 U.S.C. § 262 and accompanying United Stated Food and Drug Administration ("FDA") regulations pertaining to defendant's diphtheria, tetanus, and whole-cell pertussis ("DTP") vaccine (trade name TRI-IMMUNOL®).

2. I have been informed by counsel for Wyeth that the minor plaintiff was administered a dose of TRI-IMMUNOL® vaccine on April 1, 1992, and that the lot at issue was manufactured in 1991 by American Cyanamid Company ("Cyanamid"). Cyanamid was a predecessor-in-interest to Wyeth, as detailed below.

BACKGROUND

3. I received a Ph.D. in Pharmacology from West Virginia University in 1972. In 1975, following three years of military service, I began working at Cyanamid. At that time, Cyanamid was an independent pharmaceutical company, headquartered in Wayne, New Jersey. Among other things, Cyanamid manufactured and distributed certain childhood vaccines, including TRI-IMMUNOL®, through its unincorporated

division, Lederle Laboratories ("Lederle"). In March 1993, I was named Director, Domestic Regulatory Affairs (Alternate Responsible Head) for Lederle-Praxis Biologicals, a business unit of Cyanamid.

4. In November 1994, American Home Products Corporation ("AHPC") acquired Cyanamid. My responsibilities at AHPC remained the same as they had been at Cyanamid.

5. Before it acquired Cyanamid in November 1994, AHPC and Cyanamid were competitors in the pharmaceutical industry. AHPC manufactured and sold, among other products, its own diphtheria, tetanus, and whole-cell pertussis vaccine under the trade name TRIPLE ANTIGEN, through AHPC's subsidiary, Wyeth Laboratories, Inc. ("Wyeth Labs"). Wyeth Labs stopped selling TRIPLE ANTIGEN in 1984. TRIPLE ANTIGEN was different from, and competed against, TRI-IMMUNOL®. TRIPLE ANTIGEN was manufactured under FDA License No. 3, while TRI-IMMUNOL® was manufactured under FDA License No. 17.

6. Following AHPC's acquisition of Cyanamid, the files and records for TRI-IMMUNOL® (which had been manufactured and sold by Cyanamid) came under control of AHPC. In March 2002, AHPC changed its name to Wyeth.

7. I held the position of Senior Director, Global Regulatory Affairs, Wyeth-Lederle Vaccines from October 1996 through 1999. From October 1996 through December 1997, I also served as Wyeth's designated Responsible Head. Under the federal regulations in effect at that time, the designated Responsible Head acted as liaison between the manufacturer and the FDA on all matters relating to compliance with federal rules and regulations. In

1997, changes in FDA regulations allowed companies to designate more than one "Authorized Official" with responsibilities for particular areas. From December 1997 through 1999, I was one of the primary Authorized Officials for all Wyeth-Lederle vaccines.

8. Vaccines are biological products (as distinguished from pharmaceutical products)[1] and are subject to pervasive federal supervision, monitoring, and control by the FDA pursuant to the Public Health Service Act (42 U.S.C. § 201 et seq.) and the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.).

9. Because of my employment at Cyanamid and Wyeth, I have personal knowledge of the laws and regulations governing the licensing of biological products, including vaccines. I am also familiar with those records Wyeth maintains pertaining to the licensing submissions to the FDA for TRI-IMMUNOL® and with the procedures Cyanamid and Wyeth followed to comply with legal requirements relating to those submissions.

TRI-IMMUNOL®

10. TRI-IMMUNOL® immunizes children against the deadly diseases of diphtheria, tetanus ("lockjaw"), and pertussis ("whooping cough"). TRI-IMMUNOL® was a highly regulated biological product that could not be distributed without express governmental approval. FDA regulations addressing every aspect of the design, manufacture, testing and labeling of vaccines applied to TRI-IMMUNOL®.

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[1] Biological products include "any virus, therapeutic serum, toxin, anti-toxin, or analogous product applicable to the prevention, treatment or care of diseases or injuries of man." See 21 C.F.R. § 600.3(h).

11. At the time of the vaccination at issue in this case, TRI-IMMUNOL® had been on the market in the United States for nearly 50 years. On April 27, 1943, the National Institute of Health ("NIH")[2] approved TRI-IMMUNOL® for marketing in the United States on the basis that the NIH had previously licensed each of TRI-IMMUNOL®'s constituent antigens: diphtheria, tetanus, and pertussis. A true and correct copy of correspondence from the NIH, dated April 27, 1943, is attached hereto as Exhibit A.

12. On March 5, 1948, because of a change in applicable regulations, Cyanamid submitted a license application for TRI-IMMUNOL®. A true and correct copy of the March 5, 1948 Application and Report on Manufacture of Diphtheria-Tetanus Toxoids, Alum Precipitated, and Pertussis Vaccine, Combined, which represents the form in effect for license applications during this time period, is attached hereto as Exhibit B.

13. On March 15, 1948, the NIH issued a license to Cyanamid for TRI-IMMUNOL®. A true and correct copy of correspondence from the NIH, dated September 28, 1949, which confirms the March 15, 1948 licensure, is attached hereto as Exhibit C.

14. On July 11, 1953, Cyanamid submitted an amended license application for TRI-IMMUNOL®, which requested approval for a modified manufacturing process involving a different aluminum adjuvant. A true and correct copy of the July 11, 1953 amended license application is attached hereto as Exhibit D.

15. On August 13, 1953, the NIH issued a license to Cyanamid for TRI-IMMUNOL®, Diphtheria and

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[2] Prior to 1972, the NIH was the federal agency responsible for the regulation of biologics.

Tetanus Toxoids and Pertussis Vaccine Combined Aluminum Phosphate Adsorbed. A true and correct copy of the August 13, 1953 license is attached hereto as Exhibit E.

16. On July 29, 1970, the NIH issued a new product license to Cyanamid for TRI-IMMUNOL®, Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed. The NIH issued a new license at this time because an amendment to Part 73 of the Public Health Services Regulations required changes to the proper names for licensed products prepared from Diphtheria Toxoid, Tetanus Toxoid, Pertussis Vaccine, Poliomyelitis Vaccine, and combinations of these products. A true and correct copy of the July 29, 1970 NIH letter and the new license is attached hereto as Exhibit F.

17. The 1970 license was in effect when the lot at issue was manufactured in 1991, and when the minor plaintiff was administered a dose of TRI-IMMUNOL® vaccine on April 1, 1992.

18. The 1970 license remained in effect until 1998. On August 14, 1998, Wyeth notified the FDA[3] that it had decided to discontinue the manufacture of TRI-IMMUNOL®, and requested that the product be withdrawn without prejudice. On October 1, 1998, the FDA notified Wyeth that the Product License for TRI-IMMUNOL® was revoked, effective October 1, 1998. True and correct copies of the August 14, 1998 letter and the October 1, 1998 letter are attached hereto as Exhibit G and Exhibit H, respectively.

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[3] Responsibility for the regulation of biologics was transferred from the NIH to the FDA in 1972.

LABELING APPROVAL

19. The FDA approved the package insert enclosed with the TRI-IMMUNOL® vaccine administered to the minor plaintiff. A true and correct copy of the Transmittal of Labels and Circulars Form endorsed by the FDA on February 26, 1990, is attached hereto as Exhibit I.

20. At the time of the minor plaintiff's vaccination, the approved labeling for TRI-IMMUNOL® complied with all applicable labeling and warning requirements. A true and correct copy of the TRI-IMMUNOL® package insert at issue is attached hereto as Exhibit J.

21. Based upon material contained in Wyeth's files relating to TRI-IMMUNOL®, and my experience as Responsible Head and Authorized Official, I believe that Cyanamid and Wyeth complied, in all material respects, with the requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act that are applicable to the licensing and labeling of TRI-IMMUNOL®.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in Chestnut Ridge, New York, this 11th day of May 2007.

/s/ DENNIS J. FOLEY
Dennis J. Foley, Ph.D.

EXHIBIT A

[Logo Omitted]
DIVISION OF BIOLOGICS CONTROL

FEDERAL SECURITY AGENCY
U.S. PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF HEALTH
BETHESDA, MARYLAND

April 27, 1943

Mr. Edwin Voigt
Lederle Laboratories
Pearl River, New York

Dear Mr. Voigt,

Pursuant to your telephone conversation with Doctor Workman this morning, we wish to advise that we have not recommended thatr license be issued for your combined Diphtheria Toxoid-Tetanus Toxoid-Bacterial antigen made from Pertussis bacilli, which you market under the trade name "Tri-Immunol". License for the mixture is not required since you are now licensed for each of the constituent antigens.

As indicated in your letter of April 19, 1943, the labels which you submitted are satisfactory. You should also have received our release of the same date for lot 233-H-11.

Very truly yours,

/s/ M. V. VELDEE
M. V. Veldee, Chief
Division of Biologics Control

EXHIBIT B

March 5th
1948

Dr. M. V. Veldee, Chief
Biologics Control Laboratory
National Institute of Health
Bethesda 14, Maryland

Dear Doctor Veldee,

We are herewith enclosing our application for license for Diphtheria-Tetanus Toxoids, Alum Precipitated, and Pertussis Vaccine, Combined.

Accompanying this license application is a protocol on Lab. No. 1945-11, and a sample of material derived from this lot is being sent to you under separate cover.

The vial labels, package circular, and printed boxes are being prepared in accordance with your comments on the preliminary proofs of this literature previously submitted to you for examination. Final copies of this literature will be forwarded to you as soon as they are available.

If you have any questions relative to the information submitted in our license application, we would be very happy to furnish you whatever information you desire.

Yours very truly,

LEDELE LABORATORIES DIVISION,
American Cyanamid Company

H. D. Piersma, Ph.D.
Director, Human Biological Section

APPLICATION AND REPORT OF MANUFACTURE OF DIPHTHERIA-TETANUS TOXOIDS, ALUM PRECIPITATED, AND PERTUSSIS VACCINE, COMBINED

To the Sugeon-General, U.S. Public Health Service, Washington, D.C.

1. Name of establishments: Lederle Laboratories Division, American Cyanamid Company
2. Location: Middletown Road, Pearl River, N.Y.
3. Give in detail method of preparation of broth for toxin productions

Diphtheria

Deferrated N-Z amine – 4.0 mg. N per cc. of broth

Mueller's Solution II – 0.20%

Mueller's Solution III – 0.10%

pH is adjusted to 7.6.

Filled in one liter Roux bottles, with 200 cc. in each bottle.

Sterilized for 25 minutes at 15 pounds pressure.

After sterilization, sterile maltose solution is added aseptically for a total concentration of 1.7%.

Tetanus

Double strength beef heart infusion	– 25%
N-Z Case (Sheffield Farms)	– 1.5%
Dextrose	– 0.75%
Sodium Chloride	– 0.50%
Disodium hydrogen phosphate	– 0.05%
Potassium dihydrogen phosphate	– 0.0175%
Magnesium Sulfate	– 0.005%
Cystine	– 0.0125%
Tyrosine	– 0.0125%
Distilled water, q. s.	– 100 ml.

pH adjusted to 6.8 – 7.2.

Heat to 60°-70°C. and filter through a sterile press. Autoclave at 5 pounds steam pressure for 30 minutes to drive off dissolved air. Prior to inoculation, add 500 mg. of sterile reduced iron per liter of broth.

Pertussis (Vaccine produced from both broth and agar media.)

Broth Medium

N-Z amine (Sheffield Type A)	– 1.5%
Sodium chloride	– 0.5%
Potassium chloride	– 0.02%
Magnesium chloride	– 0.01%
Sodium carbonate (anhydrous)	– 0.05%
Potassium dihydrogen phosphate	– 0.025%
Calcium chloride – anhydrous	– 0.02%

Soluble Starch (Merck) – 0.10%

Cysteine hydrochloride-1% solution – 0.10%

Distilled water, q. s. – 100 ml.

pH adjusted to 7.0.

Filled into 20 liter bottles, each containing 5 liter of medium and into 50 liter bottles, each containing 15 liters. Heated 1 hour at 100°C., and then sterilized for 30 minutes at 15 pounds pressure.

Agar Medium

Same formula as for broth medium, with 3% Difco agar added. Filled into 1 liter Roux bottles, each containing 100 ml., and sterilized for 30 minutes at 15 pounds pressure.

4. Give method for growing organism for inoculations:

Diphtheria

P. W. #8 strain is grown in veal infusion broth containing 2% Proteose peptone, 0.5% sodium chloride, 0.7% sodium acetate, and 1% maltose. The medium in sterilized for 25 minutes at 15 pounds pressure, and organisms are transplanted every 24 hours.

Tetanus

Stock seed culture is inoculated into 10 ml. of nutrient broth, and incubated for 24 hours at 35°-37°C. in an anaerobic jar (chromium-sulfuric acid method). Use one seed tube per 7 liters of medium for inoculation.

Pertussis

The strains of H. pertussis used for vaccine production are transplanted tri-weekly on potato-glycerine agar enriched with approximately 35% citrated sheep blood. The growth from slants maintained at 37°C. for 48 hours is transplanted to Roux bottles containing 100 ml. potato-glycerine agar enriched with approximately 15% citrated sheep blood. After a 48 hour growth period at 37°C., the growth on this medium serves as a seed for agar-vaccine production. In the case of broth vaccine production, a 24 hour growth at 37°C. from slants is inoculated into small volumes of broth, shaken for 12-18 hours at 37°C., and this growth used as seed to plant large volumes of broth for production of vaccine.

5. How long and at what temperature is the organism grown for toxin production?

Diphtheria

8 to 10 days at 32°-33°C.

Tetanus

5 to 6 days at 35°C.

Pertussis

On agar – 48 to 60 hours at 37°C.

On broth – 12 to 18 hours at 37°C.

6. Is the purity of each flask controlled? How?

Diphtheria

Yes, macroscopically.

Tetanus

Yes, by gross appearance, odor, and microscopic examination of smears.

Pertussis

Yes, by microscopic examination of smears, and streaked blood agar plates.

7. What is the original strength of the toxin before detoxification?

	Diphtheria	Tetanus
a) M.L.D.:	1000 to 3000 per ml.	10,000 to 500,000 per ml.
b) L+ doses:	0.01 ml. to 0.025 ml.	
c) Test doses:		0.002 ml. to 0.05 ml.

8. When is the formalin added to the toxin and in what amount?

Diphtheria

0.5% formalin is added immediately after filtration of the toxin, followed by an additional 0.2% formalin 24-48 hours later.

Tetanus

0.3% formalin is added to the whole broth culture immediately before sterile filtration through a Seitz press.

Pertussis

Killing agent is sodium ethyl mercuri thiosalicylate in a concentration of 1:5000.

9. How long, and at what temperature, is detoxification allowed to proceed?

Diphtheria

Detoxification is carried out at 40°C. with a continuous passage of sterile warm air through the solution for 35 to 80 days.

Tetanus

Detoxification is carried out at 37°-38°C. for 2 weeks.

Pertussis

Killing time is approximately 7 days at 20°C. (room temperature).

10. How far is the detoxifying process carried?

Diphtheria

Until a dose of not less than 2.5 ml. (5 maximum human doses) injected subcutaneously into at least four guinea pigs weighing 300 to 400 grams causes no evidence of diphtheritis poisoning during a 30-day period.

Tetanus

Until a dose of not less than 2.5 ml. (5 maximum human doses) injected subcutaneously into at least four guinea pigs weighing 300 to 400 grams produces no evidence of tetanus poisoning during a 21-day period.

Pertussis

Until a dose of ten thousand million bacteria injected intraperitoneally into at least five 16-gram mice causes no loss in weight during the following 72 hours and no deaths attributable

to the vaccine during the period of 7 days kept under observation. The initial weight is taken just prior to injection after suitable feeding and watering at least two hours previously.

11. Give in detail method of precipitation, precipitant used, amount, and how added.

Diphtheria

Refined and concentrated diphtheria toxoid containing 800 to 1000 Lf units per ml. is used. A 10% solution of potassium aluminum sulfate is added in the proportion of 19 mg. of alum per 165 Lf units of toxoid.

Tetanus

Refined and concentrated tetanus toxoid containing 400 to 700 Lf units per ml. is used. A 10% solution of potassium aluminum sulfate is added in the proportion of 1 mg. of alum per 12 Lf units of toxoid.

Pertussis

The vaccine is not alum precipitated.

12. How many times is precipitate washed?

Diphtheria and Tetanus

The precipitate is washed once with unpreserved 0.3 M glycine solution.

13. Is precipitate made up to full volume of original toxoid from which precipitate was obtained?

The precipitated diphtheria and tetanus toxoids are combined with stock pertussis vaccine and diluted with 0.3 M glycine solution so that the final mixture contains 50 Lf units of diphtheria toxoid per ml., 16 Lf units of tetanus

toxoid per ml., and 20,000 million pertussis organisms per ml.

14. What type of bulk bottles are used for storage?

Diphtheria, Tetanus, and Pertussis

40 liter, 9 liter, and 4 liter pyrex bottles.

a) How are bulk bottles marked for identification?

All bottles are tagged with Lederle tag containing the name of the product, lot and bottle number, and date of manufacture.

15. Preservatives

Diphtheria and Tetanus

Kind and when added: Sodium ethyl mercuri thiosalicylate in a concentration of 1:10,000. Added to the final product after dilution with glycine.

Pertussis

Kind and when added: The killed stock vaccine contains 1:5000 sodium ethyl mercuri thiosalicylate. After dilution of the final product with glycine, the concentration is corrected to 1:10,000.

16. What is the size of the human dose expressed in cubic centimeters of undiluted toxoid?

The human dose recommended for use consists of three injections of 0.5 cc. each, with an interval of three to four weeks between injections.

17. Give in detail tests for safety and potency:

Safety Test

After the final labels have been affixed to the containers, enough are picked out at random from each lot of final containers to permit the intraperitoneal injection of at least two mice and two guinea pigs with the maximum tolerated quantity, not exceeding 0.5 ml. per mouse and 5 ml. per quinea pig (but at least 0.5 ml. for each guinea pig). These animals are kept under observation for 7 days and must remain alive without significant symptoms referable to the injected material.

Potency Test

Diphtheria – See Diphtheria Toxoid, Alum Precipitated, Purogenated.

Tetanus – See Tetanus Toxoid, Alum Precipitated, Purogenated.

Pertussis

Female 4-week-old white mice (9 to 12 grams) of one strain are used. Three groups of at least sixteen each are immunized by one intraparitoneal injection of 0.5 ml. of the product diluted with saline to contain in each dose 0.8 billion, 0.2 billion, and 0.05 billion, respectively. (Other suitable doses with 4-fold or 5-fold increments may be used). Similar groups of mice are injected with the same dosage of a control vaccine. Four additional groups of ten mice each are set aside as culture controls.

Ten to fourteen days following injection, the immunized mice and one group of control mice

are injected intracerebrally with approximately 100,000 H. pertussis Phase I organisms in a volume of 0.03 ml. peptone suspension prepared from a suspension harvested from a 20 to 24-hour culture on fresh 30% sheep's blood agar and adjusted turbidimetrically to contain 10,000 million organisms per ml. This challenge dose is expected to contain 100 to 200 LD_{50} doses. Higher dilutions representing approximately 2,000; 400; and 80 bacteria, respectively, are injected intracerebrally in 0.03 ml. doses into the three remaining groups of control mice. Bacterial counts are checked on blood agar plates and are expected to show a count about 1/3 that estimated by the turbidimetric method.

After injection of the challenge dose, the mice are observed daily for 14 days. Deaths occurring within 72 hours are considered nonspecific and are not counted. Other deaths are not counted unless preceded by typical symptoms of paralysis and a bulging head. Mice are counted as dead, however, if they show such symptoms on the 14th day.

Potency tests must show protection varying directly to the quantity of vaccine injected and with a difference of at least thirty between the percentages of survival obtained with the extreme doses. Each test is evaluated statistically by the Wilson-Worcester method and is considered satisfactory for release if its ED_{50} in terms of numbers of immunizing bacteria is not more than 1.4 times the ED_{50} for the control vaccine in comparative tests.

18. What is the concentration of formula in the finished product?

    Traces to negative.

19. State sizes of commercial packages:

    1 and 5 immunization packages.

20. Is the date of manufacture, or expiration date, stated on the label?

    Yes.

21. Are accurate records kept of different steps in the manufacture of each lot?

    Yes.

22. Are accurate records kept of the disposition of each lot for purpose of withdrawal if necessary?

    Yes.

Remarks: _____

_____

_____

Date of information: February 24, 1948

Signature of expert or experts responsible for the purity and potency of this product:

/s/ L. S. Danielson

/s/ [Illegible]

/s/ W. S. Hammond

/s/ H. D. Piersma

/s/ Frances L. Clapp

The foregoing statements in regard to equipment and methods are correct; any change therein which might endanger the purity or potency of the product will be reported to the Surgeon General, before adoption.

Signature of Firm: /s/ B.W. Casey, M.D.
Director
Lederle Laboratories
Division
American Cyanamid
Company

[ATTACHMENT OMITTED AS ILLEGIBLE]

[ATTACHMENT OMITTED AS ILLEGIBLE]

[ATTACHMENT OMITTED AS ILLEGIBLE]

[ATTACHMENT OMITTED AS ILLEGIBLE]

PREPARATION OF TRI-IMMUNOL

Equal quantities of diphtheria toxoid (concentrate diluted to 64 Lf per cc.), tetanus toxoid (regu. r Lf 6), and pertussis antigen detoxified (concentrated to 200 units per cc.) were thoroughly mixed in a large container. This material was Mandler filtered and then tested for potency, safety, and sterility, as described in Question #13.

EXHIBIT C

[Logo Omitted]
BIOLOGICS CONTROL LABORATORY

FEDERAL SECURITY AGENCY
U.S. PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF HEALTH
BETHESDA, MARYLAND

September 28, 1949

Doctor H. D. Piersma
Lederle Laboratories
Pearl River, New York

Dear Doctor Piersma,

Referring to your letter of September 27 pertaining to the status of your license for Diphtheria and Tetanus Toxoids, [Illegible] and Pertussis Vaccine Combined, this is to advise that our records indicate you were licensed for this combination on March 15, 1948.

You are correct in regard to Section 22.74 of the biologic regulations as indicating that a license should be issued for the triple product even though you are licensed for the individual components. You probably were advised when you originally introduced the product that the individual licenses would cover the preparation, but I believe this was before the present issue of the regulations became effective.

Very truly yours,

/s/ [Illegible]
[Illegible]
Chief, Laboratory of Biologics
Control
Microbiological Institute

EXHIBIT D

LEDERLE LABORATORIES DIVISION
American Cyanamid Company

July 11, 1953

Dr. W. G. Workman, Chief
Laboratory of Biologics Control
National Microbiological Institute
National Institutes of Health
Bethesda 14, Maryland

Dear Dr. Workman:

We are herewith submitting to you our license application on Diphtheria and Tetanus Toxoids, and Pertussis Vaccine, Combined, Aluminum Phosphate Adsorbed, together with final literature copy to be used in conjunction with the market distribution of this product. This literature was sent to you in draft copy form sometime ago for approval before printing.

An experimental lot of this product was used in the injection of approximately two hundred and fifty children in a local orphanage to establish the safety of this product for human administration. There were no reports of significant reactions following the use of this lot of material. Subsequently, approximately twenty children have been injected with Lot No. 1948-201, without unusual reactions being observed, and the diphtheria and tetanus antitoxin responses of a number of these children are being determined, but as yet are not available.

Miss Clapp has forwarded samples of Lot Nos. 1948-201, 1948-202, 1948-203, 1948-204 and 1948-206, together with protocols for these lots, to your office. In your letter of July 7 to me, you mention that upon review of the protocols of these lots, you observe that the amount of aluminum phosphate per individual injection has assayed high in some lots. Upon reviewing the protocols submitted by Miss Clapp, we note that an error has occurred in reporting the aluminum phosphate content of Lot No. 1948-203 as 6.15 mg. per injection, or 0.5 ml. volume. This should have been reported as 3.46 mg. per injection, or 0.5 ml. volume, since our assay reports show this to be 6.92 mg. per ml. Miss Clapp will make a correction of this error, in a reply to your inquiry about her experience in the intraperitoneal injection of various lot numbers of this product into guinea pigs and mice.

We appreciate your comments about the aluminum content of this product being high, since undesirable reactions following injection of this product in children may frequently be traced to this factor. The statement in the Minimum Requirements that the aluminum in an individual injection shall not exceed the equivalent of 15 mg. of alum when determined by assay always seemed to be perfectly clear to me when we were using potassium aluminum sulfate as an adjuvant. However, as it appears to me now, we never included the water of hydration in calculating the quantity of the alum contained in the solution. If so, the figures we have been reporting in the past, should be considerably higher as alum then actually reported. Apparently what we had been reporting previously as "alum" was actually the potassium aluminum sulfate in solution. In any event, it seems

that the introduction of the aluminum phosphate adsorbed adjuvant does not increase the amount of aluminum being injected into the patient in contrast to the aluminum injected when alum was used as the adjuvant. That point is being checked by a few random assays of some retention samples of alum precipitated products. I will also venture to guess that the aluminum content of the alum precipitated toxoids distributed to the market prior to the introduction of our purified toxoids, based on this interpretation of the statement in the Minimum Requirements, must have run close to 35 mg. of alum per injection. I am going to dig up some of these old samples of non-purified toxoids, and run an aluminum assay on them to check this point.

As I have indicated, Miss Clapp will write you directly regarding her experience in the safety tests on this product. We have discussed the results of your tests, and compared these with our results, and it is apparent that the guinea pig is more sensitive to the intraperitoneal injection of alum or aluminum phosphate than the mouse.

We were pleased to note the diphtheria and tetanus antitoxin responses you obtained in testing Lot No. 1948-201. We have been advised, either by telephone or by letter from Dr. Pittman, that this lot of material also passed the pertussis test satisfactorily.

We appreciate sincerely your presentation, in your letter of July 7, of the results of your tests on various lots of this new product in an effort to prevent a delay in the issuance of a license for the distribution of this product. Should other questions arise, we would be happy to supply you with whatever additional information you may desire. If you find our

license application in order, we would appreciate receiving releases on those lots of material that have passed your tests satisfactorily.

Very truly yours,
LEDERLE LABORATORIES DIVISION,
American Cyanamid Company

/s/ H. D. Piersma

H. D. Piersma, Ph. D.
Manager, Biological Production Section

HDP:lg

APPLICATION AND REPORT ON MANUFACTURE OF DIPHTHERIA-TETANUS TOXOIDS AND PERTUSSIS VACCINE, COMBINED, ALUMINUM PHOSPHATE ADSORBED

To the Sugeon-General, U.S. Public Health Service, Washington, D.C.

1. Name of establishment: Lederle Laboratories Division, American Cyanamid Company

2. Location: Middletown Road, Pearl River, New York

3. Give in detail method of preparation of broth for toxin production:

A. Diphtheria Toxin Medium:

A concentrated solution of casein digest (Sheffield N-Z Amine) containing 10 mg. N. per ml. is prepared and rendered iron-free by a method described by Mueller and Miller (Journal of Immunology, Vol. 40, No. 1, Jan. 1941). The formula for the completed medium is as follows:

Deferrated casein digest solution (N-Z Amine)

	4 mg. N/ml.
Technical maltose	1.70%
Mueller's Solution II	0.20%
Mueller's Solution III	0.10%

Distilled water q.s. to volume
pH adjusted to 7.6 after sterilization

Autoclaved for 10 minutes at 100°C., and for 25 minutes at 121°C. The maltose solution and broth are autoclaved separately, and the maltose solution added to the broth aseptically after sterilization. The formula for Mueller's Solution II is as follows:

Magnesium sulphate ($MgSO_4 \cdot 7H_2O$)	22.5 gm.
Beta Alanine	0.115 gm.
Nicotinic acid*	0.115 gm.
Pimelic acid	0.0075 gm.
Copper sulphate ($CuSO_4 \cdot 5H_2O$) – 1% solution	5.0 ml.
Manganese chloride ($MnCl_2 \cdot 4H_2O$) – 1% solution	1.5 ml.
Zinc sulphate ($Zn\ SO_4 \cdot 7H_2O$) – 1% solution	4.0 ml.
Hydrochloric Acid concentrated	3.0 ml.
Water to make up to 100 ml.	

*Nicotinic acid is dissolved separately in about 1 ml. of water and a few drops of concentrated hydrochloric acid, and then added to the other ingredients.

The formula for Mueller's Solution III is as follows:

Cystine	20.0 gm.
Hydrochloric acid concentrated	20.0 ml.
Water to make up to 100 ml.	

B. Tetanus Toxin Medium:

For the preparation of one liter of this medium, the following components are required:

Beef Heart infusion* – Double Strength	250 ml.
N-Z Case peptone (Sheffield)	15.0 gm.
Dextrose	7.5 gm.
Sodium chloride	5.0 gm.
Disodium phosphate ($Na_2HPO_4 \cdot 12H_2O$)	1.26 gm.
Potassium dihydrogen phosphate (KH_2PO_4)	0.175 gm.
Magnesium sulphate ($MgSO_4 \cdot 7H_2O$)	0.050 gm.
Cystine	0.125 gm.
Tyrosine	0.125 gm.
Reduced iron	0.500 gm.
Water to	1000 ml.

Reaction adjusted to pH 6.8 to 7.2. The reduced iron is added to each bottle of medium just prior to autoclaving, which takes place at 118°C. for 30 minutes. The broth is placed in 9 liter pyrex bottles in a volume of 7 liters per bottle.

*Preparation of Double Strength Beef Heart infusion – One liter of distilled water is added to 900 grams of finely ground, fat free beef heart tissue, and boiled for five to ten minutes. The mixture is filtered to obtain a clear filtrate.

C. Pertussis Vaccine Production Medium: This medium is a modified Cohen-Wheeler medium for the growth of H. pertussis in fluid culture.

Casamino Acids (Bacto), technical	10.0 gm.
Sodium chloride	2.5 gm.
Monopotassium phosphate (KH_2PO_4)	0.5 gm.
Magnesium chloride ($MgCl_2 \cdot 6H_2O$)	0.4 gm.
Starch, soluble, powdered	1.5 gm.
Placental digest peptone	*
Calcium Chloride ($CaCl_2$) – 1% solution	1.0 ml.
Ferrous sulphate ($FeSO_4 \cdot 7H_2O$) – 0.5% solution	2.0 ml.
Copper sulphate ($CuSO_4 \cdot 5H_2O$) – 0.5% solution	1.0 ml.
Cysteine hydrochloride – 1% solution	2.5 ml.
Yeast dialysate**	100.0 ml.
Arabinose, L+, c.p.***	0.1%
Distilled water to make	1000.0 ml.

Dissolved the dry ingredients of the medium in about 400 ml. of hot distilled water and heat to boiling to dissolve the starch. Add the other ingredients and distilled water to make about

900 ml. Adjust the reaction to pH 7.2 – 7.3 with sodium hydroxide and dilute to a final volume of 1000 ml. Filter through paper. The broth is dispensed in 750 ml. quantities in 4 liter bottles and sterilized by autoclave at 120°C. for 20 minutes.

*Diluted to a final concentration in the media of 0.76 mg. nitrogen per ml.

**Yeast dialysate:

Brewer's Yeast (Fleischman pure dry type 2019)	500 gm.
Distilled Water	800 gm.

Make a paste of the yeast with the 800 gm. of water and transfer to a cellophane dialysing tube (0.089 cm. thickness). Immerse this filled tube in 2000 ml. of distilled water and adjust for dialysing. Dialyze for 7 hours at 78°-80°C. Remove the tube and transfer the dialysate to a storage bottle. Add 5 ml. of chloroform per liter and store in the cold room.

***Arabinose Solution:

The arabinose is made up in 10% solution and autoclaved at 15 pounds steam pressure (120°C.) for 20 minutes. It is added aseptically to the final sterile medium to give a concentration of 0.1%.

4. Give methods for growing organisms for inoculation:

A. Diphtheria inoculum is grown on the following medium for 24 hours at 32°C.:

Veal infusion (500 gm. meat per 1000 ml. distilled water)

Difco proteose peptone	2.0%
Sodium chloride, c.p.	0.5%
Sodium acetate, reagent	0.7%
Calcium chloride, anhydrous	0.01%

pH 7.6 – after sterilization

Filled into 9 liter pyrex bottles for sterilization, and then filled aseptically into sterile 8 x 7/8 tubes as needed.

B. Inoculum for the production of tetanus toxin is grown on the following medium:

To one liter of double strength beef infusion is added:

Difco Bacto peptone	10.0 gm.
Sodium chloride	5.0 gm.

The solution is boiled for 10 to 15 minutes and filtered. The reaction is adjusted to pH 8.0 – 8.2, boiled 30 minutes, and filtered. The broth is then dispensed into 1 liter bottles, which are then autoclaved at 116°C. for 20 minutes, and stored in the cold. Before use, 1% dextrose is added to this medium, and it is then dispensed into pyrex test tubes in 8 to 10 ml. volumes. They are sterilized at 112°C. for 10 to 15 minutes. These tubes containing culture

medium are inoculated with 0.1 ml. of a 24 hour culture of Cl. tetani, or a recently thawed stock culture. Tubes are incubated in an anaerobe jar, and incubated for 18 – 24 hours at 35°-37°C. before use as an inoculum for tetanus toxin production. One tube of culture medium is used for each 7 liters of medium in a 9 liter pyrex bottle.

C. Inoculum for the production of pertussis vaccine is produced as follows:

The cultures are brought out from the dried state and maintained on Bordet-Gengou (sheep blood) agar; two subcultures are made from one tube for tri-weekly inoculation of broth in 4 liter bottles. The Bordet-Gengou blood agar slants are incubated at 30°-32°C. for 40-45 hours. The growth from one slant is harvested in approximately 12 ml. physiological buffered saline solution. Six ml. of this bacterial suspension are used as the inoculum for one bottle containing 750 ml. of broth.

5. How long and at what temperature are the organisms grown for toxin production?

A. Diphtheria Toxin – The production of diphtheria toxin takes place in 5-7 days, incubation at 32°-35°C.

B. Tetanus Toxin – The production of tetanus toxin takes place in 5-6 days, incubation at 35°C.

C. Pertussis Vaccine – The production of pertussis vaccine occurs in 40-45 hours, incubation at 34°-36°C.

6. Is the purity of each flask controlled? How?

   A. Diphtheria Toxin – Yes, macroscopically.

   B. Tetanus Toxin – Yes, by gross appearance, odor, and by microscopic appearance of smears.

   C. Pertussis Vaccine – Yes, by gross appearance, odor, and by microscopic appearance of smears.

7. What is the original strength of the toxins before detoxification?

	Diphtheria	Tetanus
a) M.L.D.:	1000 to 3000 per ml.	10,000 to 500,000 per ml.
b) L/ doses:	0.01 ml. to 0.025 ml.	
c) Test dose:		0.002 to 0.5 ml.

8. When is the formalin added to the toxins and in what amount?

   A. Diphtheria Toxin – 0.4% is added immediately after filtration of the toxin, the pH is adjusted to pH 7.0 – 7.2 two times during the first 7 days.

   B. Tetanus Toxin – 0.3% is added to the whole broth culture immediately before sterile filtration operations and adjusted to pH 7.0 – 7.2.

9. How long, and at what temperature, is detoxification allowed to proceed?

   A. Diphtheria Toxin – Detoxification takes place at 38°-40°C. from 70-100 days, (depending upon the original nitrogen content,) and potency of the toxin.

B. Tetanus Toxin – Detoxification takes place at 37°-38°C. for 3 weeks with frequent adjustments to pH 7.0 – 7.2.

C. Pertussis Vaccine – Sodium ethyl mercuri thiosalicylate is added in a 1:10,000 concentration to the broth culture upon harvesting the vaccine. The bacterial suspension is then centrifuged, and the supernatant is discarded. The organisms are resuspended in buffered saline solution (pH 6.8 – 7.0), containing 1:10,000 sodium ethyl mercuri thiosalicylate. This resuspension is made so that the concentration of the suspension is equivalent to about 75-125 opacity units per ml.; the suspension is incubated at 37°C. for 48 hours, at room temperature for 7-10 days, and finally stored at 3°-5°C. until both viability and toxicity tests are satisfactory.

10. How far is the detoxifying process carried?

A. Diphtheria Toxin – Until a dose of not less than 5.0 ml. injected subcutaneously into at least four guinea pigs weighing 300 to 400 gm. each causes no evidence of diphtheria poisoning during a 30 day observation period.

B. Tetanus Toxin – Until a dose of not less than 5.0 ml. injected subcutaneously into at least four guinea pigs weighing 300 – 400 gm. each causes no evidence of tetanus poisoning during a twenty-one day observation period.

C. Pertussis Vaccine – Viability tests on the efficacy of the preservative in killing H. pertussis are performed on Bordet-Gengou blood agar and in sterility medium. Toxicity of the vaccine is determined by mouse tests. Both types

of test must be passed satisfactorily before the vaccine is used for a final market product.

11. Give in detail method of precipitation, precipitant used, amount, and how added:

A. Preparation of Sterile Aluminum Phosphate Suspension at pH 5.0 – 5.5 Materials:

a) 10 percent solution (weight/volume) of aluminum chloride ($AlCI_3 \cdot 6H_2O$)

b) 15.75 percent solution (weight/volume) of trisodium phosphate ($Na_3PO_4 \cdot 12\ H_2O$)

c) 2N sodium hydroxide solution

d) 1 per cent solution of sodium ethyl mercuri thisosalicylate

e) Distilled water

Procedure:

Twenty-five liters of distilled water are put into each of four 50 liter pyrex bottles. Five liters of a 10 per cent solution of aluminum chloride are added to each bottle and then slowly, with constant stirring, five liters of a 15.75 percent solution of trisodium phosphate are added to each bottle. The suspension is mixed thoroughly. The reaction of this suspension should be about pH 5.0. Five liters of distilled water are added to each bottle. The bottles are stoppered and allowed to stand at room temperature for seven days.

After standing for seven days, twenty liters of clear supernatant are siphoned off from each bottle and discarded. The remaining 20 liters of precipitate suspension in each bottle is pooled in a tank and then re-distributed into

smaller bottles, and autoclaved at 116°C. for 30 minutes. The reaction of the suspension becomes more acid as the result of sterilization. The amount of 2N sodium hydroxide solution required per liter to adjust the reaction to pH5.3 to 5.5 is determined by titration. Using sterile technic, the calculated amount of 2N sodium hydroxide solution is added to each bottle of suspension, and a one percent sodium ethyl mercuri thiosalicylate solution is added to each bottle to give the preparation a final concentration of 1:10,000 of this preservative. Samples of the suspension are submitted for assay for aluminum phosphate content, which at this point, by calculation, is 13.725 mg. per ml. Finally, bulk sterility tests are performed on each bottle of suspension before use in a final preparation.

B. Method of Precipitation and Amount Used –

Materials:

a) Sterile, concentrated aluminum phosphate suspension, previously adjusted to pH5.0-5.5 and containing 1:10,000 sodium ethyl mercuri thiosalicylate as a preservative.

b) Sterile, concentrated, refined tetanus toxoid, containing 1:10,000 sodium ethyl mercuri thiosalicylate as a preservative.

c) Sterile, concentrated, refined diphtheria toxoid, containing 1:10,000 sodium ethyl mercuri thiosalicylate as a preservative.

d) Sterile 2N sodium hydroxide solution.

e) Sterile one percent sodium ethyl mercuri thiosalicylate solution.

f) Sterile distilled water.

Procedure:

The volume of sterile, concentrated aluminum phosphate suspension required for a finished product containing 0.5-1.5 mg. of aluminum phosphate per ml. is calculated. The volume of sterile, concentrated, refined tetanus toxoid required for the finished, adjusted mixture is calculated. This is about 12-20 Lf units per ml. in the final preparation. The volume of sterile, concentrated, refined diphtheria toxoid required for the finished, adjusted mixture is calculated. This is approximately 40-60 Lf units per ml. in the final preparation. The volume of sterile Pertussis vaccine is calculated for 27 opacity units per ml.

Using sterile technic, the measured diphtheria toxoid is added to a measured volume of aluminum phosphate suspension; the measured tetanus toxoid is likewise added to another measured volume of aluminum phosphate suspension. These separate mixtures are mixed together subsequently, as described. The mixtures of diphtheria toxoid and aluminum phosphate suspension and tetanus toxoid and aluminum phosphate suspension are thoroughly agitated and the reaction of each mixture checked; this should be about pH5.0-5.5. The mixtures are placed in an incubator at 35°-37°C. for 48 to 72 hours and then placed at room temperature. The mixtures are agitated once or twice daily to resuspend the precipitate.

The volume of sterile concentrated H. pertussis suspension required per liter of finished mixture is calculated, added to the previously mixed toxoid and aluminum phosphate suspensions and mixed. The resulting reaction is usually about pH5.5-6.0. The mixtures are allowed to stand at room temperature for 1 day then the reaction is adjusted, with sodium hydroxide solution to pH6.0-6.2. Sterile distilled water is added as required to bring to the volume originally calculated. One percent sodium ethyl mercuri thiosalicylate is added as required with the diluent in order to adjust the final concentration to 1:10,000 of the preservative.

The bottles are allowed to stand 1 day at room temperature, bulk sterility tests are made on the separate mixtures, and they are then stored at 3-5°C. When the sterility tests are satisfactorily completed, the separate mixtures are pooled in a tank, thoroughly mixed, passed through #200 stainless steel mesh and dispensed into sterile bottles. The pH is checked on one bottle. The bottles are held at room temperature for 1 day. Bulk sterility tests are made on each bottle and then stored at 3-5°C.

12. How many times is the precipitate washed?

The precipitate is not washed.

13. Is the precipitate made up to full volume of original toxoid from which precipitate was obtained?

The dilution indicated in the procedure outlined in section 11 is usually the equivalent of dilution beyond the full volume of the original crude toxoids prior to refinement operations.

14. What type of bulk bottles are used for storage?

Nine liter and forty-five liter pyrex bottles are used for storage of the components used in the manufacture of this final product.

a) How are bulk bottles marked for identification?

All bottles are tagged with a Lederle tag, which identifies the name of the product, the lot and bottle number, and the date of manufacture.

15. Preservative: Kind: Sodium ethyl mercuri thisosalicylate

Amount: 1:10,000

When added: The preservative is added to the aluminum phosphate suspension when the reaction is adjusted after autoclaving; it is added to the refined toxoids prior to final sterile filtration after completion of the refinement process, and it added to the stock pertussis suspension at the time the growth is harvested.

16. What is the size of the human dose expressed in cubic centimeters of undiluted toxoid?

The human dose recommended for use of this final product consists of three 0.5 cc. injections, with an interval of four to six weeks between each injection. The total human immunizing dose is 1.5 cc.

17. Give in detail tests for safety and potency:

A. Safety Test:

Tests are made on a final container picked out at random from each lot of final filled containers by intraperitoneal injection of not less than 0.25 ml. each in two mice, each weighing approximately 20 grams, and the intraperitoneal injection of not less than 1.5 ml. each into two guinea pigs, each weighing approximately 350 grams. These animals must remain alive without significant symptoms for a period of seven days.

B. Potency Tests:

For potency tests of diphtheria and tetanus toxoids, see license application for Diphtheria – Tetanus Toxoids, Alum Precipitated.

The potency test for the pertussis vaccine component of this product is performed as described in the Minimum Requirements: Pertussis Vaccine, 1st revision, October 31, 1952. If and when revisions are made, the necessary changes in technic and/or calculation will be made to correspond with the revisions.

18. What is the concentration of formalin in the finished product?

Traces to negative.

19. State sizes of commercial packages:

One and five immunization packages.

20. Is the date of manufacture, or expiration date, stated on the label?

    Yes

21. Are accurate records kept of different steps in the manufacture of each lot?

    Yes

22. Are accurate records kept of the disposition of each lot for purpose of withdrawal, if necessary?

    Yes

REMARKS: See Appendix A for description of other tests performed on this product.

Date of information: July 9, 1953

Signature of expert or experts responsible for the purity and potency of this product:

/s/ Frances W. Bingham

/s/ Arthur W. Tallman

/s/ Frances L. Clapp

The foregoing statements in regard to equipment and methods are correct; any change therein which might endanger the purity or potency of the product will be reported to the Surgeon General, before adoption.

Signature of Firm /s/ W. G. Malcolm

Director
Lederle Laboratories Division
American Cyanamid Company

Appendix A

The following tests are performed routinely on this product:

1. Test for Freedom from Toxicity:

   A group of 5 white mice of either sex, weighing 14 to 16 grams each, are weighed as a group at least 2 hours after they have been placed in a cage with access to feed and water and just prior to intraperitoneal injection with 0.3 ml. of the final suspension. At the end of 72 hours, the group weight must be not less than at the time of injection and at the end of 7 days it must be greater than at the time of injection and no deaths must have occurred.

2. Test for Identity:

   The contents of a final labeled container are treated with 20 mg. of sodium citrate per ml. to clear partially the suspension, which is then centrifuged at 2,000 r.p.m. for 15 minutes. The supernatant is tested for diphtheria flocculating units and the sediment is examined microscopically for organisms resembling H. pertussis. No test is made for the tetanus toxoid component, since all Lederle products containing both diphtheria toxoid and pertussis vaccine also contain tetanus toxoid.

3. Test for Sterility:

   Representative final containers selected at random from each lot of filled containers are tested for sterility by inoculating not less than one ml. per container into sufficient fluid thioglycollate medium to neutralize the sodium ethyl mercuri thiosalicylate used as a preservative. The inoccu-

lated tubes or bottles of medium are incubated at 32°C. for a period of 7 days, with subculture into fresh thioglycollate medium at the end of that time, should the suspension make the medium so turbid that the tests cannot be read. Such subcultures are also incubated at 32°C. for 7 days. If no growth appears, the test is considered satisfactory. If growth appears, the test may be repeated.

The number of containers tested depends upon the number in the lot of filled containers. If the number of containers in the lot totals 50 or less, three containers are tested. An additional vial is tested for each 50 final containers, up to a total of 10 containers for test.

EXHIBIT E

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE

FEDERAL SECURITY AGENCY
WASHINGTON

To: American Cyanamid Company through the establishment identified as Lederle Laboratories Division, American Cyanamid Company

Located at: Pearl River, New York

Subject: Product License

This Department is satisfied that the requirements of the Public Health Service Act, approved July 1, 1944 (58 Stat. 682), and the regulations in effect thereunder for the manufacture, exportation, importation and sale of any virus, serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivative or any other trivalent organic arsenic compound), have been met with respect to the following product(s):

Diphtheria and Tetanus Toxoids and Pertussis Vaccine Combined Aluminum Phosphate Adsorbed

You are therefore hereby authorized to manufacture and sell the product(s) specified above in accordance with the terms of License No. 17 issued to your establishment.

/s/ [Illegible]
Secretary

August 13, 1953

EXHIBIT F

[Logo Omitted]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

July 29, 1970

Gentlemen:

An amendment to Part 73 of the Public Health Service Regulations was published in the Federal Register on March 21, 1970, which included official changes of the proper names for licensed products prepared from Diphtheria Toxoid, Tetanus Toxoid, Pertussis Vaccine, Poliomyalitis Vaccine, and combinations of these products.

Accordingly, your licenses for the manufacture of the following products are hereby revoked without prejudice and are reissued under the new proper names, effective this date:

Old Name	New Name
Diphtheria and Tetanus Toxoids Combined Aluminum Phosphate Adsorbed	Diphtheria and Tetanus Toxoids Adsorbed
Diphtheria and Tetanus Toxoids and Pertussis Vaccine Combined Aluminum Phosphate Adsorbed	Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed
Tetanus Toxoid Aluminum Phosphate Adsorbed	Tetanus Toxoid Adsorbed
Tetanus and Diphtheria Toxoids Combined Aluminum Phosphate Adsorbed (For Adult Use)	Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use)

Please acknowledge receipt of the enclosed licenses to the Director, Division of Biologics Standards, National Institutes of Health, Bethesda, Maryland 20014.

Sincerely yours,

/s/ [Illegible]
Assistant Secretary
for Health and Scientific Affairs

Lederle Laboratories Division
American Cyanamid Company
Pearl River, New York 10965

4 Enclosures

CC: Mr. B. H. Lebois
Dr. H. D. Piersma
Dr. E. H. Swanzey

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Washington

Product License

This is to certify that American Cyanamid Company Pearl River, New York *through the establishment identified as* Lederle Laboratories Division, American Cyanamid Company *located at* Pearl River, New York *is hereby authorized to propogate or manufacture and prepare for sale the following*:

Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed

this Department having been satisfied that the requirements of the Public Health Service Act, approved July 1, 1944 (58 Stat. 682), for the regulation of biological products and of the regulations thereunder have been met with respect to the product(s) specified above.

Establishment License No. 17

Date: July 29, 1970 /s/ [Illegible]
Assistant Secretary
for Health and Scientific
Affairs

EXHIBIT G

[Logo Omitted]

Wyeth-Lederle Vaccines and Pediatrics

401 North Middletown Road, Pearl River NY 10965-1299 – (914) 732-5000
Business Unit of Wyeth-Ayerst Laboratories
Division of American Home Products Corporation

August 14, 1998

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Room
1401 Rockville Pike
Suite 200 North, HFM-99
Rockville, Maryland 20852-1448
Attn: Dr. M. C. Hardegree, HFM-400

Dear Doctor Hardegree:

In accordance with 21 CFR 601.5, we hereby inform you of our decision to discontinue the manufacture of Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, TRI-IMMUNOL®. We therefore request that the product be withdrawn without prejudice. Enclosed please find a copy of the license; we could not locate the original.

Sincerely yours,

/s/ DENNIS J. FOLEY

Dennis J. Foley, Ph.D.
Senior Director
Global Regulatory Affairs

DJF:pvz
attachment

EXHIBIT H

[Logo Omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

October 1, 1998

In reply refer to HFM-475

Divisions of Vaccines and
Related Products Applications
Telephone: 301-827-3070

Dennis J. Foley, Ph.D.
Lederle Laboratories
Division American Cyanamid Company
401 N. Middletown Road
Pearl River, NY 10965

Dear Mr. Foley:

We have been advised by your letter of August 14, 1998, that Lederle Laboratories Division American Cyanamid Company, U.S. License 0017 has discontinued the manufacturing of Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed.

Therefore, in accordance with the provisions of 21 CFR 601.5(a), Product License for Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed are hereby revoked, effective this date.

We acknowledge your inability to locate the original Product License, dated July 29, 1970, and we are therefore returning to you for your files the copy of

your Product License with a notation of revocation made thereon.

Sincerely yours,

/s/ KAREN L. GOLDENTHAL, M.D.

Karen L. Goldenthal, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Washington

Product License

This is to certify that American Cyanamid Company Pearl River, New York *through the establishment identified as* Lederle Laboratories Division, American Cyanamid Company *located at* Pearl River, New York *is hereby authorized to propogate or manufacture and prepare for sale the following*:

**[REVOKED
BY AUTHORITY OF THE
SECRETARY OF HEALTH AND HUMAN SERVICES
10-1-88]**

Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed

this Department having been satisfied that the requirements of the Public Health Service Act, approved July 1, 1944 (58 Stat. 682), for the regulation of biological products and of the regulations thereunder have been met with respect to the product(s) specified above.

Establishment License No. 17

Date: July 29, 1970 /s/ [Illegible]
Assistant Secretary
for Health and Scientific
Affairs

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DECLARATION OF JILL HACKELL

I, Jill Hackell, M.D., declare and state as follows:

1. I received an M.D. from John Hopkins University School of Medicine in 1976. I completed a residency in pediatrics at John Hopkins in 1979, and, in 1980, I completed a fellowship in ambulatory pediatrics at the University of Texas Health Sciences Center at Houston. After practicing as a clinical pediatrician for four years, I joined American Cyanamid Company ("Cyanamid") in 1984. Among other things, Cyanamid manufactured the diphtheria, tetanus, and whole-cell pertussis ("DTP") vaccine (trade name TRI-IMMUNOL®). Cyanamid was acquired by American Home Products Corporation ("AHPC") in November 1994, and, in March 2002, AHPC changed its name to Wyeth. I retired from Wyeth in January 2007, at which time I was an Assistant Vice President of Scientific Affairs and Research Strategy. A true and correct copy of my curriculum vitae through my retirement, which sets forth my educational background and my employment history with Cyanamid, AHPC and Wyeth, is attached hereto as Exhibit A.

2. I make this declaration in support of Defendant Wyeth's Third Motion for Summary Judgment to address what I understand to be allegations by plaintiffs about Cyanamid's post-marketing surveillance for TRI-IMMUNOL®. Specifically, I make this declaration to show that Cyanamid complied with federal law regarding post-marketing surveillance for TRI-IMMUNOL® during the period at issue. I have been informed by counsel that the lot of TRI-IMMUNOL® at issue was manufactured by Cyanamid in 1991 and was the source of the vaccine administered to the minor plaintiff on April 1, 1992.

3. When I joined Cyanamid in 1984, I held the position of Associate Director, Professional Medical Services. I was responsible for providing technical information to health professionals with respect to, among other things, the TRI-IMMUNOL® vaccine. My position also included responsibility for the development of package inserts and the review and analysis of adverse reports for vaccines, including TRI-IMMUNOL®.

4. From July 1988 – March 1989, I held the position of Associate Director, Clinical Research and Medical Affairs and from April 1989 – August 1994, I held the position of Director, Clinical Research and Medical Affairs at Cyanamid. In both positions I continued to have responsibility for supervising the development of package inserts and the review and analysis of adverse event reports for vaccines, including TRI-IMMUNOL®.

TRI-IMMUNOL® PRODUCT LABELING

5. TRI-IMMUNOL® is a combination of three immunizing agents: tetanus toxoid, diphtheria toxoid, and whole-cell pertussis vaccine, adsorbed. TRI-IMMUNOL® was used in the routine immunization of children in this country against the deadly diseases of diphtheria, tetanus ("lockjaw") and pertussis ("whooping cough").

6. I am informed by counsel that plaintiffs' Amended Complaint alleges that, following receipt of the vaccine at issue, minor plaintiff has a seizure and "was subsequently diagnosed with a residual seizure disorder and a severe neurological injury." Moreover, counsel informs me that plaintiffs specifically allege, "Defendant either knew or should have known the actual incidence of adverse reactions was higher,

and that Defendant under-reported the incidence of adverse reactions in the relevant package insert".

7. Wyeth's records show that the package insert in effect for the lot of TRI-IMMUNOL® administered to minor plaintiff in this case bears the number DX 16 and was revised in 1989. A true and correct copy of the relevant TRI-IMMUNOL® package insert is attached hereto as Exhibit B.

8. With respect to adverse reactions, the TRI-IMMUNOL® package insert states, among other things, that "[t]he incidence of convulsion or transient shock-like episode occurring within 48 hours of vaccination has been estimated to be 1 per 1,750 doses". See Exhibit B. In support of this statement, the package insert cites to Cody C. et al., Nature and Rates Of Adverse Reactions Associated With DTP and DT Immunizations in Infants and Children, Pediatrics (1981), a true and correct copy of which is attached hereto as Exhibit C.

9. The adverse reaction rate for convulsion or transient shock-like episode occurring within 48 hours of vaccination as published in the relevant package insert remained current as the date of minor plaintiff's Immunizations in April 1992. No newly published medical literature warranted amending the package insert during this time period.

10. The TRI-IMMUNOL® package insert also states that "encephalopathy has been reported following pertussis vaccination; one study suggests that incidence of encephalopathy occurring within seven days of vaccination may be 1 per 140,000 doses, with encephalopathy resulting in death or permanent damage to the central nervous system estimated to occur in 1 per 330,000 doses." See Exhibit B. In support of this statement, the package insert cited to

Miller DL et al., Pertussis Vaccine And Whooping Court As Risk Factors In Acute Neurological Illness And Death In Young Children, Dev. Biol. Stand. (1985), a true and correct copy of which is attached hereto as Exhibit D.

11. The adverse reaction rate for encephalopathy occurring within seven days of vaccination and encephalopathy resulting in death or permanent damage as published in the relevant package insert remained current as of the date of minor plaintiff's immunization in April 1992. No newly published medical literature warranted amending the package insert to increase the adverse reaction rate during this time period.

ADVERSE EXPERIENCE REPORTING

12. At the time I joined the company in 1984, Cyanamid consistently followed standard operating procedures in place for collecting adverse experience reports associated with all vaccines, including TRI-IMMUNOL®, for submission to the United States Food and Drug Administration ("FDA"). A true and correct copy of sample Drug Experience Reports exemplifying the type of adverse experience report submitted to the FDA at this time is attached hereto as Exhibit E.

13. Cyanamid reported to the FDA reports received of adverse events after receipt of it vaccines, including any contraindicating adverse events occurring after receipt of TRI-IMMUNOL®, as specified in the product's package insert. As set forth in the relevant package insert here, contraindicating reactions for TRI-IMMUNOL® that would have constituted reportable events included "any type of neurological symptoms or signs, including one or more

convulsions (seizures) following administration" of the vaccine. See Exhibit B.

14. Cyanamid had policies and procedures in place to comply with its adverse event reporting obligations as set forth by the FDA.

15. Cyanamid's policies and procedures resulted in the company materially complying with its obligations under federal law to conduct post-marketing surveillance of adverse experiences associated with TRI-IMMUNOL®.

16. I know of no adverse event report associated with the administration of TRI-IMMUNOL® that was event intentionally withheld from the FDA.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in New City, New York this 17th day of May, 2007.

/s/ JILL HACKELL
Jill Hackell, M.D.

DEFENDANT WYETH, INC.'S STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF ITS THIRD MOTION FOR SUMMARY JUDGMENT

Defendant Wyeth, Inc. ("Wyeth") respectfully submits the following Statement of Undisputed Facts in Support of its Third Motion for Summary Judgment under Rule 56(b) of the Federal Rules of Civil Procedure:

1. Minor plaintiff received the DTP vaccine at issue in this action in April 1992. See Compl. ¶¶ 8-10; Plaintiffs' Response to Defendant Wyeth's Statement of Undisputed Facts in Support of Wyeth's Motion for Summary Judgment (Docket No. 29) ("Response to Statement") ¶ 1.

2. In April 1992, the childhood vaccination schedule recommended by the Advisory Committee on Immunization Practices ("ACIP") of the federal government's Center for Disease Control ("CDC") included the administration of FDA-approved DTP vaccine at approximately 2, 4, 6, and 15-18 months, and 4-6 years of age. See Wyeth. Inc.'s Brief in Support Of Its Motion For Summary Judgment Pursuant To Fed. R. Civ. P. 56(b) (Docket No. 22) ("Wyeth's First Motion") Ex. 4; Response to Statement ¶ 2.

3. The minor plaintiff received her first three DTP vaccinations in accordance with the ACIP's recommendations. See First Am. Compl. ¶¶ 7-9; Response to Statement ¶ 3.

4. Born on October 20, 1991, minor plaintiff allegedly received a dose of DTP vaccine on December 3, 1991, February 4, 1992, and April 1, 1992. See First Am. Compl. ¶¶ 7-9; Response to Statement ¶ 3.

5. After receiving her third dose of DTP vaccine in April 1992, minor plaintiff allegedly experienced

a seizure and was subsequently diagnosed with "residual seizure disorder" and "developmental delay." See First Am. Compl. ¶¶ 10-11; Response to Statement ¶ 5.

6. The pertussis component in TRI-IMMUNOL® consists of "whole-cell" pertussis vaccine – a suspension of whole, killed pertussis cells. See Wyeth's First Motion Ex. 7; Response to Statement ¶ 6.

7. On December 17, 1991, the FDA approved Wyeth's product license application for a DTP vaccine containing an acellular pertussis component (trade name ACEL-IMUNE®). See Wyeth's First Motion Exs. 8, 9; Response to Statement ¶ 7.

8. The FDA's approval in 1991 allowed Wyeth to market and distribute ACEL-MUNE® only for the fourth and/or fifth shots in the five shot series, i.e. for toddlers who had previously been immunized with three or four doses of whole-cell DTP vaccine. See Wyeth's First Motion Exs. 8, 9; Response to Statement ¶ 8.

9. The FDA did not approve any acellular pertussis vaccine for all five doses of the recommended DTP vaccination series (among children aged 6 weeks to 6 years) until 1996. See Wyeth's First Motion Exs. 10, 11; Response to Statement ¶ 9.

10. On July 31, 1996, the FDA licensed Connaught Laboratories, Inc. to distribute Tripedia® – "the first acellular pertussis vaccine to be licensed in the United States for the first three doses of the diphtheria, tetanus, and pertussis vaccination series." See Wyeth's First Motion Ex. 10; Response to Statement ¶ 10.

11. The FDA's approval of ACEL-MUNE® for all five doses of the recommended DTP vaccination

series followed in December 1996. See Wyeth's First Motion Ex. 11; Response to Statement ¶ 11.

12. At the time of minor plaintiff's April 1992 vaccination, no alternatively designed DTP vaccine was approved by the FDA for children her age. See Wyeth's First Motion Exs. 10, 11; Response to Statement ¶ 12.

13. In 1992, Lederle Laboratories ("Lederle") was an unincorporated division of American Cyanamid Company ("Cyanamid"), an independent pharmaceutical company. See March 27, 2006 Memorandum and Order (Docket No. 13) ("Order") at 2; see also Affidavit of Bradford A. Lewin, Esq., dated December 23, 2005 ("Lewin Aff.") ¶¶ 2-3 (attached to Response and Opposition of Defendant Wyeth, Inc. to Plaintiffs' Motion to Remand) (Docket No. 5).

14. Lederle manufactured a DTP vaccine with the trade name TRI-IMMUNOL®, the vaccine at issue in this case. See Order at 2; Lewin Aff. ¶ 3.

15. American Home Products Corporation ("AHPC") acquired Cyanamid in November 1994. See Order at 2; Lewin Aff. ¶ 2.

16. In March 2002, AHPC changed its name to Wyeth. See Order at 2; Lewin Aff. ¶ 4.

17. Until 1984, AHPC's subsidiary, Wyeth Laboratories, Inc. ("Wyeth Labs") sold its own diphtheria, tetanus, and whole-cell pertussis vaccine under the trade name TRIPLE ANTIGEN. See Declaration of Dennis Foley, Ph.D., dated May 11, 2007 ("Foley Dec.") ¶ 5.

18. At all times that TRIPLE ANTIGEN was manufactured by Wyeth Labs, that Company was entirely unrelated to Cyanamid, and the two companies manufactured different vaccines, at different

locations, under different FDA licenses. See Foley Dec. ¶ 5.

19. From March 15, 1948, when the National Health Institute first issued a product license to Cyanamid for TRI-IMMUNOL®, until 1998, when AHPC voluntarily discontinued the manufacture of TRI-IMMUNOL®, Cyanamid, and after November 1994, AHPC, held a valid product license for TRI-IMMUNOL®. See Foley Dec. ¶¶ 12-18.

20. The FDA approved the package insert enclosed with the TRI-IMMUNOL® vaccine administered to the minor plaintiff. See Foley Dec. ¶ 19.

21. Cyanamid and Wyeth complied, in all material respects, with the requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act that are applicable to the licensing, labeling of TRI-IMMUNOL®. See Foley Dec. ¶ 21.

22. Cyanamid had policies and procedures in place to comply with its adverse event reporting obligations as set forth by the FDA. See Declaration of Jill G. Hackell, dated May 17, 2007 ("Hackell Dec.") ¶ 14.

23. Cyanamid's policies and procedures resulted in the company materially complying with its obligations under federal law to conduct post-marketing surveillance of adverse experiences associated with TRI-IMMUNOL®. See Hackell Dec. ¶ 15.

24. The lot of vaccine that was the source of the TRI-IMMUNOL® administered to the minor plaintiff on April 1, 1992 passed all required testing, including potency and toxicity testing of the pertussis vaccine. See Declaration of Dr. Mary B. Ritchey, dated April 2, 2007 ¶ 29.

Dated: May 18, 2007

Respectfully Submitted,

s/ Reetu Dandora
Michael T. Scott
Reetu Dandora
REED SMITH LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, Pennsylvania 19103
(215) 851-8100
COUNSEL FOR DEFENDANT
WYETH, INC.

Of Counsel:

Daniel J. Thomasch
Lauren J. Elliot
Holly M. Dellenbaugh
ORRICK, HERRINGTON &
SUTCLIFFE LLP
666 Fifth Avenue
NewYork, NY 10103
(212) 506-5000

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

[Filed June 18, 2007]

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT WYETH, INC.'S THIRD MOTION FOR SUMMARY JUDGMENT, AND IN FURTHER OPPOSITION TO WYETH'S PENDING MOTIONS FOR SUMMARY JUDGMENT

[TEXT OMITTED]

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

VIDEOTAPED DEPOSITION OF JANE M. BRECK, M.D., a witness herein, called by the Defendants for examination, in accordance with the Federal Rules of Civil Procedure, taken by and before Ann Medis, Registered Professional Reporter and Notary Public in and for the Commonwealth of Pennsylvania, at the Children's Hospital of Pittsburgh Legal Department, 220 Meyran Avenue, Suite 123, Pittsburgh, PA 15213, on Wednesday, April 4, 2007, commencing at 10:19 a.m.

* * * * *

[72]

* * * * *

Q. Are you aware, as you sit here today, that the lot of DTP vaccine given to Hannah Bruese-

witz on April 1 had reports of 65 adverse events, including 39 emergency room visits, six hospitalizations and two deaths?

A. No.

Q. Would you have liked to have known before April 1, 1992 that over 30 adverse events were reported and one death was reported from the lot of DPT vaccine that you were about to administer [73] to Hannah Bruesewitz?

A. Yes.

Q. Would the knowledge of the adverse events including the death have changed your decision to vaccinate Hannah Bruesewitz with that particular lot of vaccine on April 1, 1992?

A. Yes, with that lot.

Q. With that knowledge of adverse events including one death, would that cause you to defer vaccination on April 1, 1992 and evaluate alternatives?

A. I would like to vaccinate to protect the patient, but not use that lot.

* * * * *

EXHIBIT D

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
Bethesda, Maryland 20014

cc: Mr. Ross
Mr. C. Hagan – AHP
Mr. M. Altin – AHP
Dr. Tint
Dr. McCarthy
Mr. Gray
Mr. Hewlett

March 9, 1978

Dr. Alan Bernstein
Wyeth Laboratories, Inc.
Wasp and Biddle Streets
Marietta, PA 17547

Dear Dr. Bernstein:

This is in response to your letter of October 28, 1977 concerning the use of the Lilly trademark, TRI-SOLGEN(R).

As I indicated to you earlier, we have consulted with our General Counsel representative about this matter. The significant issue with regard to the TRI-SOLGEN(R) name is the question concerning the extent to which Wyeth intends to employ the Lilly manufacturing method. It seems clear that this name would be applicable to a product manufactured by Wyeth using the same manufacturing methods and strains employed by Eli Lilly in their licensed product. Substitution of other DPT components or other adjuvants for those in the Lilly product raises the question that use of the TRI-SOLGEN(R) name

might constitute mislabeling. Use of the same name for a reformulated product presents a significant potential for confusion because the product is no longer identical to the product with which the consumers are familiar. As you suggest this problem might be remedied by incorporating an appropriate disclosure of the change(s) in the labeling and advertising for the product which would indicate the new formulation. However, even if the change in formulation was minor it would be essential that the difference between the Wyeth and Lilly product be clearly indicated in the labeling.

It is difficult to be more specific until you are able to define in more detail the formulation of the product to be marketed by Wyeth and the modifications that are intended in its preparation. We understand that this issue is of considerable importance to you, so that there will be no misunderstanding it would be wise, once you have a clearer idea of your plans, to send them to us so that we will be able to make a final evaluation of the use of the TRI-SOLGEN(R) name and the proposed labeling.

Sincerely yours,

/s/ PAUL [ILLEGIBLE]

for Harry M. Meyer, Jr., M.D.

EXHIBIT E

Lederle

Biological Section – May 15, 1975

Mr. R. R. Johnson

R. J. Vallancourt

Reactions to Diptheria & Tetanus Toxoids & Pertussis Vaccine (TRI-IMMUNOL®)

Reactions to TRI-IMMUNOL®, unfortunately, can be expected with this product. We relate this to the pertussis component primarily. Lederle has a whole cell vaccine, while the leader in the field (Eli Lilly) has a disrupted cell vaccine (TRI-SOLGEN®), which apparently is less reactive.

We have recently purchased DPT from Marrell-National and we have a documented case of problems with their vaccine also (see attached). This in no way says that we lack concern about these reactions; only that we have learned to expect them. Pertussis vaccine acts as an adjuvant also; therefore, it is possible that reactions to the other components are exaggerated in the presence of this vaccine.

Some years ago we spent several thousands of dollars in product and process improvement and had little success in solving the problem. I am not suggesting we initiate any development work at this time, for the product line could not support it. I would suggest:

a. that we approach Lilly for its pertussis vaccine process and/or,

b. continue to bid on foreign contracts for this product line with the intent of increasing volume to a point where the product(s) will support a development effort, or

c. both of the above.

I do not at this time regard these reactions as a developing trend towards problems with the product. The Biological Section is monitoring all complaints and a record is kept so that at any given time, if there is a clustering of complaints in a given lot, we become aware of it.

RJV:mr R. J. Vallancourt

Attachments

EXHIBIT F

AMERICAN CYANAMID COMPANY
LEDERLE LABORATORIES
PEARL RIVER, NEW YORK

Biological Process and Product Improvement Laboratory

PPIL VOLUME V

TYPE OF REPORT:	Progress Report No. 4
PROJECT NUMBER	51334
REPORTED BY	M. V. Quarry
WORK DONE BY	W. A. Baroun and M. V. Quarry
PERIOD COVERED	FROM 6/9/64 TO 7/21/65
REPORT ISSUED	12/2/65
APPROVED BY	/s/ M. S. Cooper
	M. S. Cooper

NOTEBOOK NO.	PAGES
65B	178-200
86B	1-153

Title

Non-Cellular Pertussis Vaccine

Origin and Purpose of Problem

Killed, whole-cell pertussis vaccine, when injected, is known to cause many undesirable reactions. One of our competitors, Eli Lilly, has successfully developed a non-cellular pertussis vaccine and claims reduced frequency of reactions, which, in turn, has swung the triple vaccine (diphtheria, tetanus, pertussis) market in their favor. This report describes some preliminary attempts to prepare a non-cellular

pertussis vaccine more reaction-free than killed, whole-cell vaccine.

Summary and Conclusions

Of the published methods examined describing the preparation of a non-cellular B. pertussis antigen, the Barts and a modified glycine-extraction procedure appears the most promising. Limited success with the Dutch procedure, which is a modified Barta procedure, has been obtained.

B. pertussis charcoal-agar cells lysed with sodium desoxycholate (DOC-Barta procedure) has produced a non-cellular protective antigen in about 40% yield. Sterile filtration of non-cellular antigen through a 0.45u porosity Millipore filter results in an additional 50% loss of protective activity. H.I.H. potency and toxicity requirements of unfiltered antigen in mice have been met frequently. Sterilization with formalin appears promising and additional purification studies are in progress.

Comparative testing for histamine sensitizing factor (HSF) and protective antigen are being studied to determine if the former test can be utilized for routine screening, thus saving time and money. The results to date are inconclusive.

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1. DOC procedure.

IV. Discussion

I. Introduction

Killed, whole-cell pertussis vaccine has been used for years to immunize infants against B. pertussis. Undesirable side reactions following vaccination, such as erythema, swelling, induration, lymph node swelling, fever, diarrhea, vomiting and spasm, are common. In addition, encephalomelitis, is a somewhat rarer but very serious side reaction. The B. pertussis cell is composed of a capsule containing agglutinegen and hemagglutinin, a cell wall containing protective antigen, histamine-sensitizing factor and endotoxin, and protoplasm containing heat-labile toxin and other antigenic components. Many investigators have reported the preparation of a soluble or non-cellular B. pertussis vaccine with various degrees of protective activity and toxicity in mice. However, clinical information in humans is very limited. Pillemer et al. (1) reported the preparation of a soluble antigen by the sonic disruption of B. pertussis cells and adsorption of the supernatant with red cell stroma. Sutherland (2) described the preparation of a cell-wall antigen by the disintegration of whole cells with ballotini glass beads in a Mickle tissue disintegrator. The resulting cell-wall fragments were treated with sodium lauryl sulphate, followed by trypsin. This preparation was reported free of toxin and histamine-sensitizing factor (HSF). Munoz and Hestekin extracted acetone-dried B. pertussis cells, after rupture in a Ribi press, with saline and used this antigenic preparation for further purification on starch gel. A protective fraction in low yield was eluted from the starch gel but this also contained HSF. To date, all attempts to separate protective activity and HSF have been unsuccessful, and it is speculated that they are closely associated, if not

identical. Barta (4, 5) lysed B. pertussis with sodium desoxycholate to free soluble antigen which was then further purified with benzathene and proflavibe. Using the Barta (4) method for lysis of B. pertussis, Hemert, Wezel, and Cohen (6) treated the extract with ribonuclease and deoxyribonuclease to degrade nucleic acids and then passed the solution through a Sephadex G-75 column to remove sodium desoxycholate. A fraction of the eluate contained protective antigen and HSF. A U.S. patent to Behrens and Ensminger (7) describes the extraction of B. pertussis with 2% phenol at 37°C, and in another patent to Dahlstrom (8), the extraction is done with one molar sodium chloride, pH 10 and 2°C. Both patents claim the preparation of a satisfactory protective antigen. In passing, mention should be made of futile attempts to repeat the other findings in many of the published reports for the preparation of soluble B. pertussis antigen.

This report describes attempts to duplicate some of the above-mentioned procedures and presents experiments that center around the Barta (DOC) (4) method for the preparation of a non-cellular B. pertussis antigen.

II. Materials and Methods

A. Materials

1. Charcoal-agar and tank B. pertussis cells were supplied by either Department 440 or 401. The preparation of these B. pertussis cells will be the subject of another report.

2. Sodium desoxycholate (DOC), Difco purified powder.

3. Normal serum albumin was prepared as described in report PPIL IV, 1-27, March 28, 1963.

4. Millipore filters were of sterilizing porosity, 0.45μ.

5. Formalin, Formaldehyde U.S.P.

6. Betaprone, Testagar and Co., Detroit, Michigan.

7. Ethylene oxide, Matheson Co.

8. Rivanol, also known as Ethodin (Winthrop Labratories).

9. Aluminum hydroxide, prepared by Department 450.

10. All other chemicals used were of reagent grade.

B. Methods

1. Barta (DOC) procedure: Centrifuged charcoal-agar, tank or bottle B. pertussis cells were suspended in 0.85% saline to 40 opacity units per ml. at pH 8.4. An H.I.H. opacity standard and Klett colorimeter with a No. 42 filter was used for the above adjustment. A 20% solution of sodium desoxycholate (DOC) was prepared in 1M $NaHCO_3$ at pH 8.4. Enough of this solution was added to the cell suspension to make a final concentration of 0.5%. The mixture was held at +2°C for 16.5 hours and the opacity unitage determined. A reduction in opacity of about 75% was usually observed. After centrifugation at +2°C and 13,000 rpm in a high speed attachment to the International PR 2, the supernatant was dialyzed for 48 hours against two changes of 0.01M PO_4 buffer at pH 7.6, and finally against 0.025M PO_4 buffer at pH 7.4 for 24 hours. Dialysis was performed at + 2°C and the bag contents contained 1:10,000 merthiolate except when sterilization experiments were being studied. Residual sodium desoxycholate was present after dialysis. The contents of the cellulose casings

were assayed for protective potency and occasionally for HSF potency. In other experiments, the DOC antigen was filtered through a Millipore of 0.45μ porosity before assay.

2. Protective and HSF potencies were determined by standard operating procedures of Department 811.

3. Toxicity was determined by Department 401.

4. Centrifugation studies were done in a Spinco preparative centrifuge at 40,000 rpm equal to 106,000 *x* g. The resulting precipitate was resuspended with the aid of a Waring blender in 0.85% saline for assay.

5. Sterilization procedures: Formalin was added to unfiltered DOC antigen to a concentration of 0.1%. After standing at 20°C for 48 hours, an equal molar amount of $NaHSO_3$ was added to neutralize excess formalin. Betapro was added to unfiltered DOC antigen to a final concentration of 1%. The mixture was stirred for one hour at +2°C. Ethylene oxide, at -20°C, was added to unfiltered DOC antigen to a final concentration of 0.5%. After four days at +2°C, the mixture was warmed to 25°C for five hours to expel excess ethylene oxide. Unfiltered DOC antigen was passed through the virus UV sterilizer at rates of 100 and 200 ml. per minute.

6. Separation of sodium desoxycholate from B. pertussis antigen: After DOC lysis and differential centrifugation; 1 M $CaCL_2$ was added in 5*X* excess to precipitate calcium desoxycholate. The precipitate was removed by centrifugation leaving a desoxycholate-free supernatant (not determined). The supernatant was dialyzed to eliminate $CaCL_2$ and assayed.

Material after lysis and centrifugation was adjusted to pH 2.5 with 1M HCl and the precipitate of desoxycholic acid removed. The supernatant was adjusted to pH 7.5 and assayed.

Regular DOC antigen (unfiltered) was treated with 0.4% Rivanol. A stringy precipitate formed which was removed by centrifugation and resuspended in 0.025 M PO_4 buffer for assay.

Regular DOC antigen (unfiltered) was treated with $Al(OH)_3$ gel to the desired concentration while stirring at +2°C for one hour at either pH 6 or 7.4. $Al(OH)_3$ plus adsorbed material was removed by centrifugation and resuspended in 0.3 M glycine containing 1:10,000 merthiolate at pH 7.4.

7. Extraction of B. pertussis cells with glycine (9): A modified method was used. Charcoal-agar B. pertussis cells were adjusted to 108 opacity units/ml. in 0.85% saline. Solid glycine was added to 0.9 M concentration at pH 7.02. The mixture was incubated at 35°C and at 5, 10 and 15 day intervals samples were removed, diluted with two volumes of water, and centrifuged at +2°C in the International PR 2 at 3,000 rpm for 40 minutes. Samples of filtered and unfiltered supernatant were assayed for protective activity.

III. Experimental

A. DOC lysis of B. pertussis cells

1. Reliability of the method

Since the B. pertussis literature describes many unsuccessful attempts of one investigator to repeat the work of others, the DOC procedure was repeated many times to determine its reliability. Lysis was performed with charcoal-agar cultivated B. pertussis cells for 16.5 hours at 2°C in the presence of 0.5%

DOC. In the early work, a screening test of Levine (10) was used to determine protective potency in mice, but this was found to be so erratic and unreliable that the standard N.I.H. potency test was adopted. Results reported in Table 1 were determined by the N.I.H. potency test. Control cells throughout this report were heated at 56°C for one-half hour before assay while all other samples were unheated. Fractions and whole cells were potency-tested at 40 opacity units/ml.

[TABLE OMITTED AS ILLEGIBLE]

[TABLE OMITTED AS ILLEGIBLE]

These results indicate that the DOC procedure is a fairly reliable method of lysing B. pertussis cells and thus yielding a non-cellular protective antigen relatively free of toxicity when tested in mice. The average yield of unfiltered antigen is approximately 40% with an additional 50% loss occurring on filtration through a 0.45μ Millipore filter.

2. Effect of normal human serum albumin during DOC lysis

Since yields of protective antigen from the DOC procedure are low, studies were undertaken with albumin present during lysis to ascertain the protective effect, if any, of this colloid. A final albumin concentration of 1% was employed. Results are summarized in Table 2.

[TABLE OMITTED AS ILLEGIBLE]

Some of the findings presented in Table 2 are rather erratic. There appears to be little difference between DOC antigen prepared by 16.5 hour lysis with or without albumin. At 88-hour lysis time there is a definite protective effect afforded the antigen by albumin but no increase in yield over that of the regular DOC procedure (16.5-hour lysis) without albumin. As also shown in Table 1, Millipore filtration causes a loss in protective potency. This would indicate, along with other evidence to be presented later, that we are dealing with a non-cellular rather than soluble antigen.

3. The effect of lysis time and 1% serum albumin on protective antigen

Since it had been shown that a substantial loss of potency occurred between the 16.5- and 88-hour lysis times without albumin, a more detailed study of the effect of lysis time with and without albumin is presented in Table 3. All experiments were performed on the same pool of charcoal-agar B. pertussis cells.

[TABLE OMITTED AS ILLEGIBLE]

Even though this experiment was controlled carefully, some erratic results are evident due partially to the fact that all potency tests cannot be done at one time. A trend is evident, as lysis time increases beyond 16.5 hours, with or without albumin, that the protective potency decreases. The data also indicate that the lysis times less than 16.5 hours should be examined. A correlation of the potency results is found in the toxicity results. As potency drops so does toxicity as indicated by the weight gain of the mice. It has been concluded that albumin has little beneficial effect on yield and could present additional problems by its presence in the final product.

4. The effect of high speed centrifugation on DOC-protective antigen

From results recorded in Tables 1, 2, and 3, it is apparent that we have a non-cellular antigen. Additional evidence was gathered from a sample of pertussis antigen supplied by the Ruks Instituut Voor De Volksgenzondheid. This material was turbid in appearance and practically all activity was lost by Millipore filtration. DOC-prepared antigen solutions, which are very slightly turbid, were subjected to a speed of 106,000 x g in a Spinco preparative centrifuge. The supernatant and resuspended precipitates were potency-tested. Results are summarized in Table 4.

[TABLE OMITTED AS ILLEGIBLE]

After the first encouraging results of experiment 86B-104.8, three additional experiments were unsuccessful. It appears that the protective antigen is composed of a spectrum of particle sizes long with antigen than can sometimes pass through a 0.45μ Millipore filter and might be termed soluble.

5. Sterilization of DOC-prepared pertussis antigen

Since Millipore sterilization of DOC pertussis antigen resulted in a loss of potency, one physical and several chemical methods of sterilization were explored. Results are summarized in Table 5.

[TABLE OMITTED AS ILLEGIBLE]

Formalin-sodium bisulfite appears promising as a procedure for the sterilization of non-cellular pertussis antigen. Unfortunately, some of the test results are unreliable due to testing difficulties. More work is needed to determine the true efficacy of this procedure. Betaprone and ethylene oxide acted as sterilizing agents but destroyed protective potency. UV, under the conditions tried, was ineffective as a sterilizing tool and there is some question as to its effect on protective potency.

6. Purification of protective antigen

Dialysis is not a very effective procedure for the complete removal of sodium desoxycholate, as the

acidification of a final antigen preparation results in the formation of a precipitate of desoxycholic acid. Techniques designed to separate protective antigen from sodium desoxycholate are summarized in Tables 6 and 7. High speed centrifugation in the Spinco, as summarized in Table 4, might also be placed in this category.

[TABLES OMITTED AS ILLEGIBLE]

Calcium choloride added to a DOC preparation forms the insoluble calcium salt of residual desoxycholic acid and probably precipitates potency as well, as indicated by a loss of protective potency in the supernatant. Adjustment of the pH to 2.5 also appears to precipitate both desoxycholic acid and protective activity. Treatment of a DOC preparation with Rivanol results in the unexplainable loss of potency in both the resulting precipitate and supernatant. Treatment of a DOC preparation with 4 mg. of aluminum hydroxide at pH 7.4 divides the protective potency equally between the adsorbed precipitate and supernatant. Under the other conditions attempted, the loss of potency cannot be accounted for.

7. Comparative HSF and protective potency testing of DOC non-cellular B. pertussis antigen

The standard N.I.H. potency test for B. pertussis requires four weeks; therefore, the investigator must either work ahead of testing results or remain idle. Munoz and Hestekin (3) and others have reported that all attempts to separate HSF and protective potency had failed, and thus took advantage of this observation by testing for HSF activity, which requires five days. Some comparative results are summarized in Table 8.

[TABLE OMITTED AS ILLEGIBLE]

It is interesting to note that potency and HSF values of tri-vaccines are nearly identical. In general, HSF potency is a higher value than protective potency but no ratio of activities can be projected. More data are being accumulated with the hope that the HSF test might at least be used for rough potency screening of experimental samples.

B. Miscellaneous procedures for the preparation of a non-cellular B. pertussis antigen

1. Attempts were made to reproduce results reported by various investigators in the preparation of a non-cellular B. pertussis antigen. The results are summarized in Table 9.

[TABLE OMITTED AS ILLEGIBLE]

Of the various methods investigated, the Dutch (6) procedure afforded slight activity and, on the basis of one experiment, the glycine-extraction procedure appears promising. Microscopic examination for intact pertussis cells of glycine-extracted cells was negative. Millipore filtration of the glycine extract caused a complete loss of potency, again stressing that we are dealing with a non-cellular rather than a soluble antigen.

C. Tank culture B. pertussis cells

1. DOC procedure

Since the success of the protein may depend on growing B. pertussis in tanks rather than charcoal-agar, the DOC procedure was applied to some preliminary B. pertussis tank runs to determine if the cells could by lysed and yield protective antigen as was found with the charcoal-agar B. pertussis cells. The results are summarized in Table 10.

[TABLE OMITTED AS ILLEGIBLE]

Some success with tank culture B. pertussis and the DOC procedure is indicated. However, it appears evident that the initial potency of tank cells must be increased to a magnitude of 50 units/T.I.D. in order to process by the DOC procedure and yield a product with sufficient potency to pass the N.I.H. requirements.

IV. Discussion

Progress in the preparation of a non-cellular B. pertussis antigen is somewhat hampered by the four-week period necessary to obtain potency results and the inherent inaccuracies sometimes encountered in the test system. Since HSF and protective potency are, to date, inseparable, perhaps as more comparable data of the two tests become available, the HSF test can be utilized as a screen for preparative fractions, thus saving time and expense.

Experiments described in this report utilize mainly chemical means of extracting protective antigen from B. pertussis cells. Physical methods of producing a non-cellular B. pertussis antigen have been avoided, to date, due to the lack of specialized equipment necessary to rupture the B. pertussis cell.

Whole B. pertussis cells exhibit considerable toxicity when tested in mice, whereas cells heated to 56°C for one-half hour in the presence of 1:10,000 merthiolate pass the N.I.H. toxicity requirements. All non-cellular B. pertussis preparations are tested unheated and exhibit tolerable toxicity in mice. Since there is no purification step in the DOC procedure except for the removal of some cellular debris, the DOC or some steps in the procedure must inactivate the toxic principle.

B. pertussis cells cultivated on charcoal-agar have almost routinely exhibited a protective potency

exceeding 50 units/T.I.D. A DOC extract of these cells affords a non-cellular protective fraction in about 40% yield. Millipore filtration of the non-cellular fraction reduces the yield an additional 50%; thus, chemical means of sterilization become important. Although charcoal-agar cultivated B. pertussis cells have been employed for most of these studies, the ultimate goal is to produce B. pertussis in tanks with sufficient potency to withstand a processing loss of 50-60%. We estimate the potency of starting B. pertussis cells should be at least 50 units/T.I.D.

Theoretically, high speed centrifugation of DOC preparations should deposit the protective antigen and effect some purification by the elimination of impurities in the supernatant. Actual experiments showed the protective potency to be divided between the supernatant and precipitate. The complete solubilization of the protective antigen appears necessary before more elaborate purification studies can be undertaken.

EXHIBIT G

INTEROFFICE CORRESPONDENCE

Mathematical Analysis April 17, 1967

Office Date

TO: Clinical Pharmacology
ATT'N OF: Dr. H. Macdonald
COPY TO: Dr. J.H. Clark
Dr. M. S. Cooper
SUBJECT: Comparison of Lilly and Lederle DPT vaccines by Dr. Blattner
REFERENCE: Statistical Job Number 2913

A double blind study to evaluate tolerance to differrent commercially available preparations containing diphtheria, tetanus toxoids and pertussis vaccine was carried out on 335 infant patients, by Dr. Russell J. Blattner.

Response to different symptoms for each patient was recorded as "Reaction" or "No Reaction".

When comparing Lilly product with Lederle the patients were classified according to the sex. Each sex, for each symptom was further detailed with respect to the first, second, third immunization or a booster and the chi-square were computed for 2 x 2 table which looked as follows:

Male

Pain (1st immunization)

	Reaction	No Reaction
Lederle	a	b
Lilly	c	d

Pooling the four different injection summary X^2_1 were computed and are summarized in table I.

On the record of one patient it was not specified if be received immunizations or booster injection and so he was eliminated from the analysis.

In case of male, for pain, irritability and temperature, Lederle injections had significantly higher rate of reaction where as in case of females, for swelling and temperature, Lederle injection had significantly higher percent of reaction, as is shown with significant X^2 in table I.

/s/ K. I. SMITH
K. I. Smith

KIS:mlv

Table I

Reaction	Sex	Lederle	Lilly	Chi-square	P
Pain	Male	42/79 = 53%	23/86 = 27%	10.10	.005*
	Female	38/87 = 44%	29/82 = 35%	.77	.500
Swelling	Male	35/79 = 44%	25/86 = 29%	3.06	.100
	Female	35/87 = 40%	17/82 = 21%	6.74	.010*
Redness	Male	18/79 = 23%	14/86 = 16%	.42	.500
	Female	22/87 = 25%	12/82 = 15%	2.25	.500
Nodule	Male	29/79 = 37%	41/86 = 48%	1.99	.500
	Female	34/87 = 39%	26/82 = 32%	.53	.500
Irritability	Male	42/79 = 53%	23/86 = 27%	10.26	.005*
	Female	30/87 = 34%	21/82 = 26%	1.51	.500
Vomitting	Male	17/79 = 22%	12/86 = 14%	.75	.500
	Female	15/87 = 17%	8/82 = 10%	1.63	.500
Anorexia	Male	12/79 = 22%	12/86 = 14%	.01	.850
	Female	21/87 = 24%	14/82 = 17%	.84	.500
Temperature	Male	43/79 = 54%	24/86 = 28%	11.82	.005*
	Female	39/87 = 45%	15/82 = 18%	14.68	.005*

* Significant at the indicated Probability Level.

EXHIBIT H

INTEROFFICE CORRESPONDENCE

Pearl River	May 18, 1967
Office	Date

TO:

ATT'N OF: Dr. I. S. Danielson

COPY TO: Dr. H. Macdonald
Mr. H. Perlmutter

SUBJECT: Clinical Evaluation of an Improved DPT Vaccine

REFERENCE:

Doctor Macdonald has recently completed a trial with Dr. R. J. Blattner wherein some significant differences in reaction rates were observed in infants receiving either Lederle Tri-Immunol or Lilly Tri Solgen.

The DOC procedure for production of non-cellular pertussis vaccine has been successful in our hands when we employ charcoal agar cells as starting material and we have completed an unofficial cost estimate which looks encouraging.

We propose to prepare, or make available, the following formulations for an additional trial by Dr. Blattner.

1. Commercial Lederle Tri-Immunol.
2. DPT vaccine containing whole cell pertussis vaccine (charcoal agar origin).

[Handwritten note: at relatively high dilution].

3. DPT vaccine containing non-cellular pertussis vaccine. The $AlPO_4$, tetanus toxoid, diphtheria toxoid, and starting cells for the pertussis component will be the identical lots used in formulation No. 2.

Doctor Macdonald proposes at least 80 subjects for each formulation. It is possible that Dr. Blattner will carry out the trial under his grant, thereby not involving any additional charges to Lederle.

The total laboratory charges for preparing the materials should not exceed $2,500.

Please advise whether we should proceed with this program.

[Handwritten notes: Ed – I think we should go ahead with this. It may be that Cooper's graph has come up with a useful pertussis preparation.
Dan]

EXHIBIT I

REPORT
OF
SPECIAL COMMITTEE
FOR
STUDY OF BIOLOGICAL BUSINESS

E. H. Dearborn
J. D. Gallagher (Chairman)
E. J. Scoble
J. W. Skinner
C. R. Wherley

June 23, 1967

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EXPLANATIONS

We define the biological business to consist of products deriving from any natural source with the exception of antibiotic fermentation products. This means that the old products generally recognized as biologicals (vaccines, toxoids, antisera, etc.) are only a part of the business and that the important broad field of peptide and protein chemistry must also be included. Therefore, we considered the business as it has been in the past and the business as we think it will be in the future. This is an important distinction.

There are only two attachments to this report. Attachment I is a package consisting of summary financial data on our existing biological product line and an overall summary page by cost center. Attachment II reflects the economic consequences of our product deletions, but the document is a distortion if considered without the offsets mentioned in the script. There is a considerable amount of additional data of various kinds that are available for inspection on request.

When we initiated this study we planned to project an income statement out to 1971. We simply could not get the required basic data generated for us with believable accuracy in a reasonable time period.

There have been no discussions with International. They might have contrary views on some points.

GENERAL RECOMMENDATIONS

1. We stay in the biological business.
2. We retain, for the most part, the existing product line for as long as it makes a significant financial contribution. For 1966 on net sales of about $18 million we accrued a Net After Tax of about $2.9

million or 16% on sales. However, the business yielded a contribution to overhead absorption (after all direct costs) of $13.1 million. Although virtually all of the NAT comes from ORIMUNE, VARIDASE and Tuberculin Tinc products – the other products contribute $3 million to overhead absorption and are actually carrying charges of about $1.7 million in Fixed Overhead. The entire line carries about $5.1 million in Fixed Overhead. We don't know where we could generate the cash to cover the deficit if products coming from the non-profitable or marginally profitable cost centers were dropped. We also conclude that consideration of reductions in plant and divisional overhead exceed the terms of reference of this study.

We do not feel, however, that the marginal products can afford any significant level of selling or development support and indeed we conclude that no improvements could be made by doing so. In fact, profitability can be improved by omission of such support. We do, however, have some individual product recommendations which represent the only things that can be done to optimize the existing product line. Those recommendations follow in the EXISTING PRODUCT LINE section of this report.

3. Put increased emphasis on the field of protein chemistry. This can be done with no budgetary increases this year, because we already have a considerable capability in protein, peptide and polymer chemistry as well as immunology. Our intent in using the term "protein chemistry" is to give the broadest possible designation to the

study of complex actions and reactions which occur in vitro and in vivo.

4. Reduction in the budgeted 1967 Research and Product Improvement accounts of $1.3 million and $220,000, respectively. The details are contained in the RESEARCH and DEVELOPMENT PROGRAMS section of this report. In general, these recommendations reflect our philosophy that protein chemistry is a promising potentially profitable area of the future and that classical biologicals are diminishing in promise – particularly for the private business sector. We find that the justification for certain existing programs is poor or very difficult to run down. We concede doubts about certain programs that we have recommended for deletion – such as purified influenza. However, we feel strongly that no program should be in existence unless there is a clear justification for it which is easily obtainable by any auditor. We would be quite amenable to the reactivation of any of these programs if they can be properly justified through appropriate mechanisms.

5. Biological Research and Development should be reorganized. We are unable to reach complete agreement on all of the details. There is complete agreement on the following points:

   a. The mission to search for new products belongs in Research and this should be consolidated in one unit – probably of section size.

   b. Cost improvement and process improvement work on existing products belongs in Production.

c. Final scaleup work on new products belongs in Production.

Unanimous agreement could not be reached on the following points:

a. Product Improvement. Those who favor locating this mission in Research feel that quite frequently such programs become new product programs in that the intent is to replace an existing product with a new one and that these programs then require research skills and personnel. Leaving it in Production does not properly centralize and coordinate the research function. Also, consolidation of new product work permits better technical and financial supervision.

   Those who favor leaving it in Production believe that it works better close to Production, and that Research people will not be sufficiently interested in this type of work to do the job properly.

   Everyone agrees, however, that no matter where it is located a better review system is needed before Product improvement projects are initiated; this applies equally well to expensive process improvement programs.

b. "Intermediate" Development. This is essentially pilot plant level work. There is disagreement as to whether this should be under Research or Production supervision. Therefore, the disagreement centers around the point of transfer from Research to Production.

6. Our bidding practices and philosophies be reviewed. Although we are not aware of all the factors affecting a given bid at a given time, we have found situations in which we have lost money or generated a very low return even on a Cash Cost basis.

   Profitable bidding practices will be of increasing importance as governmental activity increases in the preventive medicine field. Although not of the same magnitude as in the private sector, profits can be made. To this end every effort must be made to keep costs down including the consideration of less expensive packages.

7. Consideration of a new marketing plan in the private sector for our old or conventional biologicals. Mr. Lebeis has given preliminary legal approval of these suggestions.

   This part of the biological business is expected to expand in relationship to the population of private practitioners. Since it is not profitable to spend salesmen's time in promoting these products to the doctors, better methods of selling this market need to be explored. The major biological outlets now – and in the future – are:

   a. Drugstores that stock and sell significant quantities of vaccines.

   b. Surgical supply houses.

   Both outlets have as a part of their business the supplying of biological products to doctors. There are approximately 800-1,000 of these outlets throughout the country. They are, for the most part, already known by our salesmen. A special

biological contract or agreement should be developed that would be designed to:

a. Place adequate inventories in these strategically located stores.

b. Give the stores an incentive to sell Lederle biologicals.

c. In addition, this same kind of a biological marketing plan could be extended to large clinics and hospitals.

In another words, these outlets would perform most of the selling and distribution functions. Although the contract or agreement would be offered to all accounts, it would be of interest only to the 800-1,000 referred to above.

8. We need to continue to improve the commercial guidance of the search mission. We must find better ways to research markets so that potentials for products which have no current market can be better defined. We have to improve the matching of the technical objectives of our research with the market objectives. We must improve our capacity to estimate costs of bringing a product to market at an earlier date. The earlier availability of refined estimations of introductory commercial expense would also be helpful to this objective.

EXISTING PRODUCT LINE

We grouped all the products in the existing line into nine cost centers. After reviewing each product individually, we were able then to assess the consequences of individual product actions on that product's cost center. A summary of the economic details for each product is reflected in Attachment 1 and, if

necessary, more detailed information is available in the individual product work sheets, which we have ready for inspection. We excluded the laboratory diagnostics in the CLAD proposal.

I. Department 460 – Diagnostic Agents (Mainly Allergenics)

[redacted]

II. Department 413 – Serum Stable Unit

[redacted]

III. Department 440 – Bacterial Vaccine

[redacted]

Tri-Immunol – This market is dominated by Lilly because of the better pertussis component in the product. The U.S. sales are almost entirely in the 7.5 cc. vial. The reverse appears to be true for International. We have spent $334,000 cumulative over prior years and have a 1967 budget of $80,000 for trying to get an improved pertussis component. The effort is not worth it for the total market. Recommendations –

1. Drop the 1.5 cc. vial.
2. Drop the development project.
3. Retain the 7.5 cc. vial until its cash contribution drops to a level of about $20,000 and then drop the product.

[redacted]

IV. Department 471 – Polio Vaccine and Measles Vaccine

[redacted]

V. Department 430 – Chicken [Illegible] Virus Production

[redacted]

VI. Department 450 – Gamma Globulin Production

[redacted]

VII. Department 516 – Enzyme Production

[redacted]

VIII. Department 433 – Smallpox Vaccine

[redacted]

IX. Tuberculin

[redacted]

Summary of Product Deletions

[redacted]

Economic Consequences of These Deletions

Attachment II reflects a contribution to overhead loss of $598,483 and $347,691 of remaining overhead with which we would have to deal. However, there are important offsets obtained by switching the business from the deleted products to other products in our line. For example, the losses from [redacted] and [redacted] will be offset by at least equivalent gains in our remaining products. These products alone account for $274,000 of the $598,000 contribution to overhead loss.

In addition, Attachment II also reflects $140,000 loss from the [redacted]. We recommended further investigations before this line was dropped.

RESEARCH AND DEVELOPMENT PROGRAMS

We are recommending reduction in the budgeted 1967 Research and Product Improvement accounts of $1.3 million and $220,000, respectively. We urge that government contracts be obtained where feasible, but we are prepared to recommend on a purely economic basis that should government support be unobtainable, the program should not be supported by us. We acknowledge that there may well be other reasons to take contrary action, but we feel an examination of those reasons is beyond the terms of reference of this committee. As explained in the General Recommendations, we would not be adverse to reactivation of any program that can be justified on better grounds than we were able to uncover.

The deletions and alterations recommended are as follows:

Research Account

[redacted]

Pertussis	
Drop	$90,000 (Plus ($80,000 (in the (Prod. (Imp. (Acct.)

[redacted]

We recommended the deletions because either the technical objectives were unrealistic or the technical problems were either insurmountable or required a disproportionate amount of effort for the return, or the costs to bring the product to market were disproportionate to the projected market potential.

[redacted]

The Pertussis program is budgeted for $90,000 (and an additional $80,000 in the Product Improvement Account). It has the objective of getting a cell-free Pertussis component for inclusion in Tri-Immunol with the hope that this would produce a less reactive product. The total market is about $1 million a year and Lilly has half of it because of a superior product. The best that we could reasonably hope for would be to have a product equal to Lilly's which would increase our sales from the current level of $150,000 to about $1/2 million per year. In order to get this with a well entrenched Lilly product as a competitor would be costly in selling expense. The effort is certainly not commensurate with the gain. However, the Biological Development people feel that they now have a cell-free Pertussis. Mr. Scoble has asked them to estimate what the additional cost would be to prove to ourselves that the product is as good as Lilly's and to bring it to market. Should the information be unexpectedly favorable the project can always be reactivated.

[redacted]

Product Improvement Account

Pertussis Vaccine Development

Drop. See discussion under Research Account $80,000

[redacted]

$220,000

/s/ J. D. GALLAGHER

J. D. Gallagher, M.D.
Chairman

EXHIBIT J

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 05-5994

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Plaintiffs,

v.

WYETH, INC., F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH-LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Defendant.

Videotape deposition of DR. MARY RITCHEY, taken on behalf of the Plaintiff, at the Pearl River Hilton, 500 Veterans Boulevard, Pearl River, New York, commencing at 10:12 a.m., February 6, 2007, before Anthony Armstrong, a Notary Public and Certified Shorthand Reporter of the State of New York.

* * * * *

[119]

* * * * *

BY MR. FABRY:

Q. When did it become clear to Lederle that the – producing a vaccine by including the Takeda acellular pertussis component would be successful sooner?

A. Well, again, it had to be sometime probably in [120] the late eighties that we made that – mid to late eighties I think we made that decision. And we still had the internal program, you know, at least for the time of the approach we made the decision to go with the Takeda vaccine, and the decision for the infant doses I believe came a little later because we were still participating in some clinical studies with our own in-house version while we were preparing to put in our license application for the Takeda acellular pertussis components for the fourth and fifth doses.

Q. So in the late 1980s, it became clear to Lederle that the – using the Takeda acellular vaccine component would be more successful sooner.

What is it that made that clear to you?

MS. ELLIOT: Objection to the question. It's not – it's not exactly the witness's testimony. It's a lack of foundation.

A. Well, as I said before, we looked at the fact that the Takeda had experience in quite a number of children with their vaccine, and we were able to collect data on that experience, and I think the fact that you know, they had experience making it, they had made a number of lots. We were able to get some clinical information from them, and we were able to put [121] together a formulation that FDA agreed with us we could use. You know, those things collectively said to you probably pursuing the vaccine using the Takeda acellular pertussis component would be the best thing at least as far as the toddler indication was concerned.

Q. Let me come at it from a little different angle. You used the term successful.

A. Uh-huh.

Q. And what did you mean by that when saying that the Takeda – using the Takeda acellular pertussis vaccine would more likely be, I think you said, more successful sooner?

A. Sooner, yes.

Q. What did you mean by successful in that sense?

A. Well, successful means that it's safe and efficacious for your purpose in using it in the toddler population.

Q. Did you have indications in the late 1980s that the vaccine developed with the Lederle-developed acellular pertussis component would not be safe and efficacious?

A. No. It's just that we didn't have much experience. Takeda had made a number of lots. They [122] had data in children. Whereas, our own vaccine at the time Takeda had some data, we didn't have any human data. So if you look at the picture of, well, how long will it take you to put together enough information and clinical studies to apply for a license, well, when we reviewed the two options, it became clear that the Takeda component if we use that instead of our own, that the most likely event is that we could do that sooner than we could if we continued to work on our own for that toddler indication.

Q. So you relied on a lot of the data that had been accumulated by Takeda in toddlers on your investigational new drug application?

A. Well –

MS. ELLIOT: Objection.

A. They had some data, but we actually had to go accumulate the data ourselves. Knowing that they

had used it in children, we knew that there was data to be gathered. So our clinical group put together a program to collect that data. You know, it wasn't data that you could just take from Japan and bring here. You had to actually go to Japan and collect the data that would be required to satisfy FDA.

* * * * *

EXHIBIT K

STATE OF ALABAMA §
§
COUNTY OF JEFFERSON §

AFFIDAVIT OF DONALD H. MARKS, M.D., Ph.D.

On this day, Donald H. Marks, M.D., Ph.D., appeared before me, the undersigned notary public. After I administered an oath to him, upon his oath, he said:

1. My name is Donald H. Marks, M.D., Ph.D. I am over the age of 18 years and competent to make this affidavit.

2. I have over 20 years of experience in pharmaceutical medicine. I am a member of the American Association of Pharmaceutical Physicians and the Regulatory Affairs Professional Society. I have been the Associate Director for Clinical Research, Antibacterials at Hoffman LaRoche Pharmaceuticals, and the Director for Clinical Research at Connaught Pasteur Merieux Vaccines. I am familiar with the process of manufacturing Diphtheria, Tetanus and Pertussis (DTP) vaccine and particularly the pertussis component of the vaccine.

3. During my time as clinical researcher in vaccines at Connaught, the concept of "Hot Lots" came up during many conversations, was well-known within the company to Clinical and other researchers, and within the vaccine manufacturing community in general. As discussed below, I did not make up the term "Hot Lots'. It is my under-

standing that all manufacturers of Whole Cell Pertussis vaccine experienced the same problem.

4. Attached as Exhibit 1 is an October 3, 1977 letter from Charles J. Masur, M.D., Professional Services at Lederle, to a Dr. Tiss. This letter provides a simple description of what came to be known as "Hot Lots":

> It has been observed that in clinical experience there may be statistical "runs" of excessive or no reactions but that in a large enough sample these uneven distributions are smoothed out. In a DTP vaccine, most reactions are due to the Pertussis component.

5. The Pertussis component of DTP vaccine is initially manufactured in a "batch", which might be released in the market with three to four different sequential "lot" or "control" numbers. The term "lot" thus can refer to a batch or can also be used to refer vaccine released with a specific control number. In the case of Hannah Bruesewitz, the control or lot number was 314-958.

6. Hence, you see in Exhibit 2, an October 14, 1977 Internal Lederle memorandum, the description "Change batch several months ago because of reactions" and a 70%-80% reaction rate" with reference to Control Number 504-224. Because excessive reactions ware reported on Control Number 504-224, the batch was changed rather that producing more vaccine lots from that batch. Changing the batch would be done to manufacture a vaccine that caused fewer reactions. That is, to prevent the release of mote "Hot Lots" from the same batch.

7. Exhibit 3 is a letter to Dr. Masur at Lederle Laboratories regarding Tri-Immunol (DTP) Vaccine Lot No. 507-228 dated December 12, 1977. The author states that "reactions continue to occur at an unprecedented rate" and was "therefore obliged to withdraw the vaccine." This appears to be yet another example of a "Hot Lot".

8. I am aware from my employment with Connaught of publicity and controversy arising out of the deaths of eight children within one week of receiving DTP vaccine manufactured by Wyeth Laboratories. A copy of the HEW press release regarding these deaths was transmitted to Dr. Vallancourt at Lederle from Dr. Paul Parkman at the Bureau of Biologics on March 27, 1979. See Exhibit 4 attached. As reported in the HEW press release, on March 12, 1979, the Tennessee Department of Health placed a hold on the use of the lot of vaccine to investigate the four deaths that had occurred within 24 hours of DTP vaccination. They discovered that four additional infants had died within a week of having been vaccinated with this lot of vaccine, bringing the total to eight infant deaths. These were referred to as sudden infant death or SID cases. Consequently, Wyeth Laboratories voluntarily agreed to withdraw all unused doses of the lot of vaccine at the request of the Food and Drug Administration (FDA).

9. The reality of the recurring "Hot Lots" and the desire to avoid identification of Hot Lots, is sadly reflected in the reaction of manufacturers to the events in Tennessee. Exhibit 5 is an internal Lederle document with "regard to reporting SIDS to BoB (Bureau of Biologics) by phone followed by

monthly summary". The author, Lederle employee Stewart Aiston writes that "each case should be reported individually, at once, by memo. This would be particularly important in case of litigation. We would not want several cases in a summary be discovered by Plaintiff's counsel." Of note, with particular reference to Hannah Bruesewitz and the seizures or convulsions that began within hours of her receiving the DTP vaccination, is the post script. Clearly Lederle was hiding the incidence of convulsions from the BoB by treating them as "minor complaints". The post script states that "since we have not in the past reported minor complaints such as fever, convulsions, etc., to the BoB, any reference to previous complaints should be avoided." No medical or public health justification exists for avoiding reports of SID cases and other reactions to the BoB in summary form. Reports in summary form would be the best way to identify "Hot Lots".

10. Exhibit 6 is yet another demonstration of the existence of "Hot Lots" by virtue of Wyeth's reaction to the tragic events in Tennessee. The August 27, 1979 internal correspondence from Alan Bernstein to Larry Hewlett at Wyeth begins with the following statement: "After the reporting of the SID cases in Tennessee, we discussed the merits of limiting the distribution of a large number of vials from a single lot to a single state, county or city health department and obtained agreement from the senior management staff to proceed with such a plan." No medical or public health justification exists for the policy described in the August 27, 1979 correspondence of "limit-

ing distribution of a large number of vials from a single lot to a single state, county or city health department," allocating stock to provide the "maximum variety of lot numbers" at their distribution centers, or prohibiting their distribution centers from filling "any order with stock exceeding 2,000 packages of one lot number." The only possible justification for this change in policy would be to hide or obscure deaths and severe adverse reactions that were occurring from a single lot of DTP vaccine. In other words, to avoid identification of "Hot Lots".

11. Although I am not certain when the term "Hot Lot" came into official usage, it does appear on Exhibit 7, a March 15, 1982 Department of Health and Human Services Memorandum regarding "Reaction Reports Associated with the Administration of DTP vaccine – Abcesses/SID's". You will find on page 3 of the memorandum, in the middle of the page, "Also appears on CDC Hot Lot List".

12. Attached as Exhibit 8 is a May 16, 1984 memorandum from Harrison C. Stetter, M.D., Medical Epidemiologist at the Department of Health and Human Services and John R. Mullen, Public Health Advisor at the Department of Health and Human Services regarding "Investigation of Potential Hot Lots". This memorandum provides what I understood to be the official definition of a "Hot Lot": "Fill lots that exceeded a threshold of $\geq$ 2 deaths, or $\geq$ 2 convulsions, or $\geq$ 10 total reports".

13. Suggesting that compliance with regulatory requirements for DTP vaccine containing a Whole

Cell Pertussis component provides an assurance of safety is simply false. The mechanism by which the vaccine generated immunity, as well as adverse reactions, was poorly understood. It was well understood, however, that the testing required before a lot could be released on the market did not provide for a standardized product with a reasonable degree of safety. In particular, it was well known for many years that the mouse toxicity test did not correlate with rections in human children. In other words, passing the mouse toxicity test provided no assurance regarding the number or severity of reactions that would occur when the same vaccine was actually administered to human children,

14. As Dr. Ronald J. Vallancourt, the Manager of the Biological Section and Responsible Head for Lederle under the Code of Federal Regulations testified, "what I'm saying, we run a test in animals here prior to shipping that vaccine out. We must pass those tests and then the Bureau of Biologics does the same thing and then they release the product. So what I am saying is that once the vaccine leaves here, it is from an animal point of view, it is safe and now we know effective and pure and potent and so on. Once it's injected into the human, if there is an adverse reaction which we've admitted there is, we have no tests that would eliminate those reactions. If we did, we'd be more than happy to have instituted them long before this." Page 170; Lines 10-21, deposition of Dr. Ronald J. Vallancourt taken in Malek, The Pines of America, Circuit Court State of Illinois, County of Cook, Cause No. 80L

28117, taken Monday, March 1, 1982 attached as Exhibit 9.

15. The limited understanding of DTP vaccine and its toxicity is well exemplified by the words of P.A. Nielsen of Lederle Laboratories in the attached Exhibit 10: "These vaccines are presumably detoxified to the extent that they must pass a mouse toxicity test. However, even with this treatment, several active antigenic substances are probably being injected along with the so-called 'protective antigen'. Since all of the substances vary independently (and are probably under genetic control), a vaccine may very likely be a variable and unstandardized mixture".

18. Dr. Piersma of Lederle Labs wrote on August 10, 1965, in a memo with the heading "Quality Control," regarding pertussis vaccine: "Unfortunately, the Division of Biologics Standards of the U.S. Public Health Service has recognized a rather poor test for freedom of toxicity of pertussis vaccine. This mouse test has many defects, among which is the variability of different strains of mice to pertussis vaccine and the fact that there never has been an effort to relate to toxicity tests in mice with toxicity of the vaccine children." See Exhibit 11 attached.

17. In Exhibit 11, Dr. Piersma and others at Lederle pointed out the following with regard to the mouse toxicity test: "The present test is without a fixed reference point, and this weakness in the test has caused manufacturers in the United States considerable distress from time to time." The numbers and severity of reactions to "Hot Lots" that were released in the market after

passing the mouse toxicity test did indeed cause considerable distress.

18. It was Dr. Piersma's view that "most manufacturers, if not all, feel that the mouse toxicity test for Pertussis vaccine, does not test vaccine as much as it does mice." He explained that in a "collaborative study varied reactions were observed by various manufacturers to the response in test mice for the toxicity of that particular vaccine. In short, some reported that there were four percent deaths using that vaccine, others as high as 43 percent deaths using that vaccine and this meant that we weren't testing the vaccine for toxicity as much as we were testing the mice, the strains of mice used by the various laboratories for toxicity." Page 112/Line 3 – Page 113/ Line 3, deposition of Henry D. Piersma taken Thursday, July 9, 1987 in *Crowe v Lederle Laboratories*, Supreme Court of the State of New York, County of Broome (and 10 other cases) attached as Exhibit 12.

19. The history of the mouse toxicity test is important to understand. Again quoting Dr. Piersma and others from Exhibit 11: "In view of the recognition by clinicians about 30 years ago that pertussis vaccine could be responsible for severe reactions, and in an effort to reduce the incidence of these reactions, the regulatory officials of the National Institutes of Health felt strongly that a toxicity test in a laboratory animal was essential. Consequently, a toxicity test for pertussis vaccine was first introduced as a requirement by the Federal Government of the United States when it issued its minimum requirements: Pertussis vaccine, under date of March 25, 1948. Certain

of the reactions were recognized to be "severe and result in permanent damage to the central nervous system." The memo points out several problems with the mouse toxicity test that were identified in subsequent years, however, "chief among these problems is the urgent need to relate the sensitivity level of the present mouse toxicity test to the sensitivity level of toxicity of this product when administered to humans."

20. Charles R. Manclark was employed by the Bureau of Biologics, Food and Drug Administration. He made the following observations in 1975 at a seminar entitled "Pertussis Vaccine: Current Status" held during the 75th Annual Meeting of the American Society for Microbiology in New York City. "We know that Pertussis vaccines passing the required toxicity and safety test can cause adverse reactions in children. Local reactions are relatively common, and include adema, erythema, induration, pain and sometimes ulcerations at the injection site. Severe reactions are less common but include fever, collapse, seizures, persistent screaming, and rarely, paralysis and death. Adverse reaction rates are not accurately reported, but more adverse reactions are probably experienced with the use of pertussis vaccine than with other biologicals. (Manclark, C.R. 1976. "The Current Status of Pertussis Vaccine: An Overview". Advances in Applied Microbiology 20:1-7. New York: Academic Press.) See Exhibit 13 attached.

21. Concerns about vaccine safety, and the DPT vaccine in particular, and threats by manufacturers to stop making vaccines if they were not given some protection from lawsuits, resulted in pas-

sage of the National Childhood Vaccine Injury Act in 1986. The Act mandates post marketing surveillance which occurred in the form of the Vaccine Adverse Advent Reporting System (VAERS).

22. As described in the attached Exhibit 14 from the Department of Health and Human Services, Public Health Service Food and Drug Administration/Centers for Disease Control, "VAERS" was created by the Food and Drug Administration (FDA) and Centers for Disease Control and Protection (CDC) to receive reports about adverse advents which may be associated with vaccines. Although the VAERS data has many uses, one of the most important applications while DTP vaccine with Whole Cell Pertussis was on the market was to identify "Hot Lots". The following quotes from Exhibit 14 reflect this application:

> The FDA continually monitors reports to determine whether any vaccine or vaccine lot has a higher than expected rate of events.
>
> * * *
>
> We also analyze patterns of reporting associated with vaccines and vaccine lots.
>
> * * *
>
> The FDA continually looks for lots that have received more serious reports that (sic) should be expected on the basis of such factors as size, time and use, and chance variation. When such a lot is detected, further investigations are initiated that could lead to recall of the lot under some circumstances.

23. Because manufacturers of DTP vaccine with a Whole Cell Pertussis component had no reliable method for detecting or evaluating the level of toxicity or reactogenicity before the vaccine was released on the market and injected into children, monitoring reactions, and the VAERS system in particular, provided the quality control necessary to identify "Hot Lots".

24. The (VAERS) data regarding Lederle Lot/Control No. 314-958 are attached as Exhibit 15. The vaccine administered to Hannah Bruesewitz was from Lot 314-958, which generated a total of 65 adverse event reports, 16 reports of convulsions, and two deaths following vaccination. This meets the CDC's definition of a DTP Hot Lot in all three categories. Considering Lot/Control Numbers produced from the same batch, the number is even higher.

25. It should be emphasized that VAERS is a passive reporting system in that it receives reports of adverse events, but does not affirmatively follow or determine the reaction every time a vaccine is administere. Consequently, it is generally accepted that the actual incidence of reactions is higher than the number that is recorded for a particular lot of vaccine in VAERS.

26. Furthermore, as demonstrated by Exhibit 15, Lot/Control No. 314-958 received 33 adverse event reports, including two deaths and eight reports of convulsions, before Hannah Bruesewitz received her vaccination on April 11, 1992.

27. I agree and sympathize with the testimony of Dr. Breck, the physician who administered this vaccine to Hannah Bruesewitz in April 1, 1992.

When asked what she would have done if she had known before April 1, 1992 that the lot of vaccine that she was about to administer to Hannah Bruesewitz had generated over 30 adverse events reports and one death, she responded: "I would like to vaccinate to protect the patient, but not use that lot." Deposition of Jane Brock, M.D., page 72, line 16 through page 73, line 13.

28. In my opinion, Lot/Control No. 314-958 was a "Hot Lot": a lot of vaccine was unusually or excessively reactogenic.

/s/ DONALD H. MARKS

Donald H. Marks, M.D., Ph.D.

SWORN TO and SUBSCRIBED before me by Donald H. Marks, M.D., Ph.D. on June 18, 2007.

[Notary Stamp Omitted]

EXHIBIT 1

cc: W.R. Currie
W.J. Fitzpatrick
J.R. Gregory
Dr. S.A. Szumski

October 3, 1977

G. J. Tiss, M.D.
101 N. Akers Road
Visalia, California 93277

Dear Doctor Tiss:

Our medical representative, Mr. John Gregory, has written to us of the adverse reactions experienced by your patients following booster injections of TRI-IMMUNOL Diphtheria and Tetanus Toxoids and Pertussis vaccine, Adsorbed.

The reactions of your report are among the adverse reactions recognized to occur with DTP vaccines. Most physicians are aware of these reactions and accept them as an acceptable risk in the prophylaxis of the diseases for which they are indicated. More often than not, we receive reports of adverse reactions to TRI-IMMUNOL from physicians who have previously used TRI-SOLGEN which is no longer available. The latter vaccine contained a fractionated Hemohilus pertussis component while all other DTP vaccines contain the whole cells. It can be expected that a vaccine consisting of less than the entire cell component of Hemohilus pertussis will give less reaction than the whole cell vaccine. (At present, there are no plans at Lederle to utilize a soluble pertussis component in the vaccine). The Efficacy Review Panel on Bacterial Vaccines and

Toxoids has issued this statement regarding the modified DTP vaccine:

> "There is one combined product presently licensed (a modified DTP) that contains a partially fractionated pertussis component and the relative efficacy of this product, compared to the whole bacterial pertussis vaccines, has not been determined in controlled field trials."

We expect that the Efficacy Review Panel will recommend to the Food and Drug Administration that license for this vaccine will be withdrawn in the absence of controlled field trials.

Adverse reactions such as you described do occur at a low incidence. It has been observed that in clinical experience there may be statistical "runs" of excessive or no reactions but that in a large enough sample these uneven distributions are smoothed out. In a DTP vaccine, most reactions are due to the pertussis component.

Felton and Varway (1) stated that almost every child who receives pertussis immunization shows some form of systemic toxicity within the first 24 hours, which may consist of irritability, anorexia, vomiting and a moderate degree of hyperpyrexia. McComb and Trafton (2) analyzed the local and systemic reactions after the first, second and third doses of a DTP vaccine; febrile reactions occurred in 9%, 12%, 14% and 7% after the first, second, third and booster doses, respectively. The percentage of local reactions was much higher and ranged from 43-58%. In a British study (3), the total incidence of all reactions, including mild ones and those they referred to as "shock of injection", were in excess of 90%.

In our clinical studies of various new and existing products, we find that large numbers of subjects involving many clinical investigators must be treated to evaluate properly the side reactions, effectiveness, etc. In almost every study, one or two investigators with large study groups will find an unusually high or unusually low incidence of adverse reactions, both of which deviate greatly from the true incidents. The deviations are not correlated with drug lot, age, sex or economic status of patient, or any other "known" variables.

From the above, it seems that the reactions to DTP Vaccine are due to the allergenic components themselves and cannot be eliminated through further refinements on the vaccine.

We regret these reactions and hope the above comments will be of interest.

Very truly yours,

/s/ CHARLES J. MASUR
Charles J. Masur, M.D.
Professional Services

CJM:srw

Official literature attached

REFERENCES

1. Felton, H. H., and Verwey, W. F. "The Epidemiological Evaluation of a Non-cellular Pertussis Antigen." Ped., 16 (November 1955) 637-650.

2. McComb, J.A., and Trafton, M. Z. "Immune Responses and Reactions to Diphtheria and Tetanus Toxoids, with Pertussis Vaccine, Aluminum Phosphate Precipitated." New Eng. J. Med., 243 (September 21, 1950) 442-444.

3. Hall, R. D., "Reactions to Diphtheria-Tetanus-Pertussis Antigen," Publ. Health, LXXIX (London) 1965.

EXHIBIT 2

10/14/77

Friday 4:10 p.m.

[Redacted] (Call Monday 10/17 after 1 p.m. EST)

TRI-IMMUNOL
Control No. 504-224
Exp. Date 1/78

Change batch several months ago because of reactions

Keeping records on lot

70-80% reaction rate

Fevers over 102°, etc.

He contacted CDC in Atlanta who told [redacted] the CDC is getting many inquiries on TRI-IMMUNOL (DPT) from all around the country.

Control No. 504-224
Batch 418B
Count 8,410 (10 x 7.5 ml vial)
Date 6/21/77

No previous complaints on this control number

RLG

EXHIBIT 5

[Handwritten Notes]

7-3-77

Ron,

With regard to reporting SIDS to BoB by phone followed by monthly summary.

Herb Runne was not in. However, Lloyd Carr believed that each case should be reported individually, at once, by memo.

This would be particularly important in case of litigation.

We would not want several cases in a summary be discovered by Plaintiff's counsel.

Stewart

PS. Since we have not in the past reported minor complaints such as fever, convulsions, etc., to the BoB, any reference to previous complaints should be avoided.

SA

EXHIBIT 6

INTERNAL CORRESPONDENCE

Wyeth

to: Mr. Larry Hewlett

company: WLD located: Radnor

from: Alan Bernstein

company: WLD located: Marietta

subject: DTP Vaccine

date: August 27, 1979

After the reporting of the SID cases in Tennessee, we discussed the merits of limiting distribution of a large number of vials from a single lot to a single state, county or city health department and obtained agreement from the senior management staff to proceed with such a plan.

This subject has been discussed with Charlie Young and the following guidelines were developed by FSRD. I would appreciate your comments concerning this procedure and the advisability of formalizing these guidelines.

Interim Measures in Affect

1. Allocation of stock to Distribution Centers is designated by lot number in a manner designed to leave the maximum variety of lot numbers in Great Valley and Marietta to service substantial orders.

2. Managers in D.C.'s carrying average inventories of over 3000 packages (approximate) have been requested to advise FSRD of any orders exceeding 2000 vials. FSRD will then designate shipment by lot number, furnishing additional stock as needed.

Permanent Policy Proposal

1. A D.C. will not fill any order with stock exceeding 2000 packages of one lot number before clearing with FSRD.
2. When additional stock is needed for compliance, FSRD will make necessary arrangements.
3. In the event that the national inventory does not permit compliance, FSRD will clear exception with Marietta management, or make arrangements for split delivery.

/s/ ALAN

Alan Bernstein

EXHIBIT 11

Recent laboratory experience in the U.S.A. with the pertussis toxicity test

H. D. Piersma, F. W. Bingham, A. E. Bolyn, A. H. Bruckner, H. A. Dettwiller, W. W. Frankhouser, D. M. Marshall and C. Newman

Lederle Laboratories,
Pearl River, New York,
U.S.A.

The quality of the pertussis vaccines used in the United States is controlled by a number of tests performed by the manufacturer, as the result of government regulations and his own internet in making a better product. These tests are designed to determine the potency, purity, safety and sterility of each lot of vaccine intended for use, whether as such, or in combination with other biological products. Before any lot of vaccine may be released for public use, however, a protocol of the tests performed by the manufacturer, together with a sample of the lot of vaccine under consideration, must be submitted to the Division of Biologics Standards of the National Institutes of Health. Upon review of this protocol, the Division of Biologics Standards may or may not decide to perform confirmatory tests on the lot under consideration. If this government agency is satisfied with a given protocol and decides that it does not wish to perform any tests on the lot submitted for release, the manufacturer is advised that the lot is approved for distribution. However, if the agency decides to perform one or more tests on the lot under

consideration, the manufacturer is advised and given an approximate date when the government tests will be completed. With a view toward obtaining a more rapid release, a manufacturer may request the government to test a lot number of his product before he has completed his own tests for this product. If the government finds it possible to test this lot simultaneously with the manufacturer, the manufacturer must, upon completion of his own tests, submit a satisfactory protocol before approval for release can be granted. When both the government and a manufacturer perform tests on a given lot simultaneously, it occasionally happens that the government test is satisfactory, while the same test performed by the manufacturer is unsatisfactory. Unless the manufacturer can show that he has obtained a satisfactory result, the government is not in a position to release that lot of product, even though the government test has been satisfactory.

The mouse toxicity test for pertussis vaccine, as formerly and presently defined for use in the United States, most likely has been responsible for a substantial reduction in the reaction rate encountered upon injection of this product in humans. We wish to point out, however, that the present test is without a fixed reference point, and this weakness in the test has caused manufacturers in the United States considerable distress from time to time. We wish to present the results of some experimental work carried out by seven manufacturers of pertussis vaccine in the United States, and discuss briefly the significance of these results.

The Toxicity Test for Pertussis Vaccine

There is general agreement among clinicians that the use of pertussis vaccine is occasionally accompanied by unfavorable reactions. Certain of these reactions are severe and result in permanent damage to the central nervous system, while other reactions are comparatively mild and transitory in nature. It has not been demonstrated that all reactions to the administration of pertussis vaccine are the result of a common cause. There is evidence, on the other hand, that some reactions are the result of idiosyncrasy on the part of a patient, while the majority of reactions appear to be due directly to the toxicity of the vaccine injected. Recently the work of Billaudelle and his coworkers[1] in Sweden has resulted in some chemical characterization of the toxic components of the vaccine.

In view of the recognition by clinicians about 30 years ago that pertussis vaccine could be responsible for severe reactions, and in an effort to reduce the incidence of these reactions, the regulatory officials of the National Institutes of Health felt strongly that a toxicity test in a laboratory animal was essential. Consequently, a toxicity test for pertussis vaccine was first introduced as a requirement by the federal government of the United States when it issued its Minimum Requirements: Pertussis Vaccine, under date of March 25, 1948.

Pittman[2] described the origin of the toxicity test as the result of studies involving the induction of skin reactions in rabbits and weight changes in mice. When a vaccine ceased to induce necrosis in a dose of 1,000 million bacteria, any weight loss induced in mice was usually regained with 72 hours. On the

basis of this correlation, a mouse toxicity test was adopted by the National Institutes of Health. Pittman discarded the rabbit skin test because of the variability of reaction from site to site on the same rabbit. Although the first description of this test involved a dosage of vaccines measured in terms of the total number of bacteria injected, this was subsequently revised so that one now uses the opacity unit as the unit of measurement of the dose administered to the test animal. A recent revision in the mouse toxicity test was made officially on August 23, 1961, and Table 1 summarizes the changes.

Experimental Work

Following the recent changes in the toxicity test for pertussis vaccine, a committee from the Biological Section of the Pharmaceutical Manufacturers Association, composed of several individuals representing many of the manufacturers of pertussis vaccine in the United States, decided to investigate certain aspects of the mouse toxicity test. As the result of experience with this test over many years, members of this committee considered it possible that various strains of mice differed in their response to a given lot of vaccine. Accordingly, the committee decided to investigate this aspect of the toxicity test. The chairman of this committee undertook to make a toxic preparation for use among various laboratories in a comparative test. The preparation was made from pertussis organisms grown on a charcoal agar medium. After harvesting the vaccine, lactose to 5% final concentration and merthiolate to 0.01% final concentration were added to the suspension, which was then adjusted to density to 100 opacity units per milliliter. Only a small amount of the supernatant of the original harvest suspension was discarded to

permit the addition of the lactose. Five days after the above treatment of the suspension, the suspension was incubated at 37°C for 24 hours. A sterility test at this time showed that there were no viable organisms in the suspension. The suspension was held at 2-5°C for 27 days from harvest and then filled into vials, and subsequently frozen and dried. Distribution of this preparation was made under identification number BD-10257.

Each of seven manufacturers was sent a supply of this toxic preparation and information for its dilution to various concentrations in terms of opacity units. Each laboratory was asked to test this preparation at least at the 7.5 opacity unit level in at least 50 mice of the strain or strains generally employed in that laboratory for the testing of pertussis vaccine. For each strain of mouse used in toxicity testing, each laboratory was also asked to collect data on the weight gains of at least 10 mice injected with 0.5 ml of sterile physiological saline, and run simultaneously with the testing of the toxic preparation. All other procedures followed in performing this toxicity test were identical to those followed in conducting the official test. The results of this study are summarized in Table 2.

It will be noted that the data here presented compares the response observed in several strains of mice to the intra-peritoneal injection of 7.5 units of the reference preparation under study. From a review of this data, it is obvious that this preparation is too toxic to pass the official toxicity test for pertussis vaccine, but certain points may be drawn from this study. First of all, it is interesting to note that the mortality rate varies from 4 to 43% for various strains of mice, and we are informed by statisticians

that this difference in mortality rate is significant. This means that a considerable difference exists in the sensitivity of various strains of mice to the lethal toxin contained in pertussis vaccine. Secondly, in looking over the column indicating the weight gain (in grams) of the mice given 0.5 ml of physiological saline only, it may be noted that one strain of mouse failed to gain an average of 3.0 grams during a 7 day observation period. This strain of mouse, accordingly, may not be used in testing vaccine in accordance with the official test for pertussis vaccine, since animals on test must gain an average of 3.0 grams over their pre-injection weight during the 7 day test. It is known that significant differences in the growth rate various strains of mice exist, and each strain has its own characteristic growth curve under normal circumstances.

Discussion

As mentioned previously, the toxicity test for pertussis vaccine, as described officially for use in the United States, most likely has served a useful purpose. Most, if not all, American manufacturers are satisfied that they have made a better product available commercially since the introduction of this toxicity test officially in 1948. However, it is also true that most, if not all, American manufacturers of pertussis vaccine recognize that the present test has limitations, which should be corrected as soon as possible.

The experimental work here presented shows that various strains of mice differ in their response to one pertussis vaccine preparation. With a spread from 4% to 43% in mortality response, one can state that certain strains of mice are relatively sensitive to the

toxic factor or factors in pertussis vaccine, while other strains are relatively insensitive. There are a number of practical considerations that follow as the result of this situation. First of all, one manufacturer may select a strain of mouse for testing his product that is relatively insensitive to the pertussis toxic factor or factors, while another manufacturer may select a relatively sensitive strain of mouse for his tests. If the Division of Biologics Standards tests the toxicity of vaccines from these two manufacturers and the sensitivity level of the mice used by the government agency lies midway between that of these two manufacturers, one manufacturer's product will be released and the other's rejected.

Unfortunately, the sensitivity of the mouse strain used routinely by the Division of Biologics Standards to the pertussis vaccine preparation used in this study has not been determined. However, in view of my comments in the introduction to this paper, namely, that a manufacturer may get a release on a lot of vaccine only if his results agree with those obtained by the Division of Biologics Standards, it also becomes apparent immediately that the sensitivity level of the strain of mouse used for toxicity testing by the Division of Biologics Standards becomes the only reference point for the present official test. It is the opinion of most of the manufacturers of pertussis vaccine in the United States that a more objective reference for evaluating the toxicity of pertussis vaccine is needed.

In addition to the establishment of an objective reference for the toxicity of pertussis vaccine, it is also recognized that other important problems exist with respect to the use of a laboratory animal test for evaluating the toxicity of pertussis vaccine. Chief

among these problems is the urgent need to relate the sensitivity level of the present mouse toxicity test to the sensitivity level of toxicity of this product when administered to humans. In order to accomplish this, we consider it imperative to recognize the difference in sensitivity levels for various strains of mice, and we hope the establishment of a reference preparation for the present pertussis toxicity test is not long delayed.

References

1. Billaudelle, H., Edebo, L. Hammarsten, E., Heden, C. G., Malmgren, B., and Palmatierna, H. Studies on the chemical and immunological structure of Bordetella pertussis, Acta Pathologica and Microbiologien Scandinavica, Vol. 50, Fasc. ?, 1968.

2. Pittman, M. Potency and toxicity of pertussis vaccine. J. Immunology, 69, 201-216, 1952.

EXHIBIT 14

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION /
CENTERS FOR DISEASE CONTROL

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

January 1, 1998 to July 30, 1999

Contents:

- Important information from the FDA about the VAERS
- Brief description of the VAERS
- Caveats to interpretation of VAERS data
- Definitions of terms used
- Description of files
- List of commonly used abbreviations used at the VAERS program

IMPORTANT INFORMATION FROM THE FDA ABOUT THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

VAERS was created by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports about adverse events which may be associated with vaccines. No prescription drug or biological product, such as a vaccine, is completely free from side effects. Vaccines protect many people from dangerous illnesses, but

vaccines, like drugs, can cause side effects, a small percentage of which may be serious. The FDA continually monitors reports to determine whether any vaccine or vaccine lot has a higher than expected rate of events.

About 85% of vaccine adverse event reports concern relatively minor events, such as ordinary fevers or redness and swelling at the injection site. The remaining 15% describe serious events, such as seizures, high fevers, life-threatening illnesses, or deaths. The reports of serious events are of greatest concern for the FDA and receive the most careful scrutiny.

The report of an adverse event to VAERS is not documentation that a vaccine cause the event. With regard to childhood vaccines, over ten million vaccinations per year are given to children less than one year old, usually between 2 months and 6 months of age. At this stage of development, infants are at greatest risk for certain medical events, including high fevers, seizures, and sudden infant death syndrome (SIDS). Some infants will by coincidence experience such an event shortly after a vaccination.

In such situations, the event may be caused by an infection, congenital abnormality, injury, or some other provocation. Because of such coincidences, it is usually not possible to be sure whether a particular adverse event resulted from a concurrent condition or from a vaccination, even when it occurred soon afterward. Therefore, doctors and other vaccine providers are encouraged to report adverse events, whether or not they believe that the vaccination was the cause. Since it is difficult to distinguish a coinci-

dental event from one truly caused by a vaccine, the VAERS database will contain events of both types.

In addition, it is often the case that more than one vaccine was administered, making it difficult to know to which of the vaccines the event might be attributed. In analyzing individual reports, we examine the medical information about the event, and obtain more specific information from the reporting doctors whenever necessary. We also analyze patterns of reporting associated with vaccines and vaccine lots.

In analyzing patterns of adverse event reporting, the FDA considers more than just the number of reports for a lot. More reports will be received for a large lot than a small one, simply because vaccine from the large lot will be given to more children. Some lots contain as many as 700,000 doses, while others as few as 20,000 doses. Similarity, more reports will be received for a lot that has been in use for a long time than a lot in use for a short time. Even among lots of similar size and time in use, some lots will receive more reports than others simply due to chance. The FDA continually looks for lots that have received more serious reports that should be expected on the basis of such factors as size, time in use, and chance variation. When such a lot is detected, further investigations are initated that could lead to recall of the lot under some circumstances.

Many complex factors must be considered in order to decide whether a lot of vaccine is unsafe. At the FDA, we apply procedures and methods of analysis to help us to understand these complex factors and closely monitor the safety of vaccines. We continually analyze these many factors to help ensure that all lots in use are safe. We hope that this brief

explanation of the factors associated with vaccines and adverse events will assist you in understanding the data you have requested.

The enclosed data set from the National Technical Information Service (NTIS) contains information releasable under the Freedom of Information Act (FOIA) concerning reports submitted to the Vaccine Adverse Event Reporting System (VAERS) from Nov 1, 1990 to the present. Under the National Childhood Vaccine Injury Act of 1986 (NCVIA) you may be entitled to more information from reports describing specific adverse events subsequent to the administration of vaccines outlined within the NCVIA. If, after examining this data set, you require more information on specific VAERS reports you may make an FOIA request utilizing the unique VAERS Report Identification Numbers contained within the enclosed data set. For each report requested, those items of information which are not disclosable, such as personal identifiers, will be purged before your request for additional information is completed. Charges for search time and copying will be made in accordance with HHS regulations.

Requests for additional information should be addressed to:

Freedom of Information Staff, HFI-35
Food and Drug Administration
500 Fishers Lane
Rockville, MD 20857

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

Brief Description of System

Background

The National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report to the Department of Health and Human Services (DHHS) specific adverse events following the administration of those vaccines outlined in the Act. DHHS established the Vaccine Adverse Event Reporting System (VAERS), which is co-administered by the Food and Drug Administration (FDA) and the Centers for Disease Control (CDC), to accept all reports of suspected adverse events, in all age groups, after the administration of any U.S. licensed vaccine. On November 1, 1990 VAERS replaced CDC's Monitoring System for Adverse Events Following Immunization (MSAEFI) for public sector reporting and FDA's Spontaneous Reporting System for private sector and manufacturer reporting. The primary purpose for maintaining the data base is to serve as an early warning or signaling system for adverse events not detected during pre-marker testing.

PLAINTIFFS' FURTHER STATEMENT OF UNDISPUTED FACTS IN OPPOSITION TO DEFENDANT WYETH, INC.'S THIRD MOTION FOR SUMMARY JUDGMENT AND IN FURTHER OPPOSITION TO WYETH'S PENDING MOTIONS FOR SUMMARY JUDGMENT AND OBJECTIONS TO WYETH'S STATEMENT OF ALLEGEDLY UNDISPUTED FACTS

Pursuant to FED. R. CIV. P. 56(c), Plaintiffs RUSSELL BRUESEWITZ and ROBALEE BRUESEWITZ, individually and an behalf of their minor daughter, HANNAH BRUESEWITZ, respectfully submit the following Plaintiffs' Further Statement of Undisputed Facts in Opposition to Defendant Wyeth, Inc.'s Third Motion for Summary Judgment and in Further Opposition to Wyeth's Pending Motions for Summary Judgment and Objections to Wyeth's Statement of Allegedly Undisputed Facts.

OBJECTIONS TO DEFENDANT WYETH'S STATEMENT OF UNDISPUTED FACTS

1. To Defendant's Statement Nos. 4-5 for use of the term "allegedly," which is inappropriate in a statement of undisputed facts. They should be removed.
2. To Defendant's Statement No. 13 for use of the term "independent," a subjective judgment inappropriate for a statement of undisputed facts. It should be removed.
3. To Defendant's Statement No. 18 for use of the phrase "entirely unrelated," a subjective judgment inappropriate for a statement of undisputed facts. It should be removed.
4. To Defendant's Statement No. 21 and 23 because they contain legal conclusions inappro-

priate for a statement of undisputed facts. They should be removed.

5. To Defendant's Statement No. 22 which is disputed because it is ambiguous. Plaintiffs will agree that Defendant had policies in place which would allow it to comply but object to the suggestion that the policies constitute compliance.

PLAINTIFFS' FURTHER STATEMENT OF UNDISPUTED FACTS

1. Eli Lilly had voluntarily requested that their license to produce the split-celled vaccine TRI-SOLGEN be withdrawn without prejudice.
2. Wyeth never marketed TRI-SOLGEN despite purchasing the right to do so in the 1980's.[2]
3. Wyeth sought approval to market TRI-SOLGEN employing adjuvants other than those used by Lilly for the same product.[3]
4. The DTP vaccine given to Hannah Bruesewitz on April 1, 1992 had previously generated reports of 65 adverse events, including 39 emergency room visits, six hospitalizations and two deaths.[4]
5. Had Dr. Breck, Hannah Bruesewitz's treating physician, had knowledge of the adverse events, including deaths, related to the vaccine lot from which Hannah Bruesewitz's vaccination was

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[2] *See* Letter from Harry M. Meyer, Jr., M.D. to Dr. Alan Bernstein, dated March 9, 1978, a true and correct copy of which is attached and incorporated as Exhibit D.

[3] *Id.*

[4] Affidavit of Donald Marks, M.D., Ph.D., at ¶ 24, a true and correct copy of which is attached as Exhibit K.

drawn, she would have changed her decision to vaccinate Hannah Bruesewitz with that particular lot of vaccine on April 1, 1992.[5]

6. Dr. Breck did not know, on April 1, 1992, that the lot from which Hannah Bruesewitz was vaccinated had previously generated reports of 65 adverse events, including 39 emergency room visits, six hospitalizations and two deaths.[6]
7. Since at least 1964, Wyeth and its predecessors in interest have been working to develop a "non-cellular pertussis vaccine more reaction-free than killed, whole-cell vaccine."[7]
8. In the mid-1960's, Eli Lilly had already developed and was marketing TRI-SOLGEN, a DPT vaccine with a non-cellular pertussis component. *Id.*
9. From the mid-1960's, Wyeth's predecessors in interest knew that an acellular vaccine was safer and less reactogenic than a whole cell one.
10. In the 1980's, Lederle, one of Wyeth's predecessors in interest, bought acellular vaccine that had been used safely in Japan from Tekeda, Japan, and put that vaccine through U.S. clinical trials. It was approved for booster shots in 1991, and all vaccinations in 1996.[8]

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[5] *See* Deposition of Dr. Jane Breck [Exh. C] at pp. 72, lns. 16-25 to 73, lns. 1-13.

[6] *Id.*

[7] *See* Progress Report, dated July 21, 1965 [American Cyanamid], produced by Wyeth as WBRSW020313, attached and incorporated as Exhibit F.

[8] *See* Deposition of Mary Ritchey, at pp. 119-122, excerpts of which are attached and incorporated as Exhibit J.

Respectfully Submitted,

/s/ JOHN R. FABRY

John R. Fabry
Fed. I.D. No. 24525
WILLIAMSKHERKHER HART
BOUNDAS, L.L.P.[9]
8441 Gulf Freeway, Suite 600
Houston, Texas 77017
Telephone: (713) 230-2284
Facsimile: (713) 643-6226

Robert E.J.Curran
Attorney I.D. No. 08620
Attorney at Law
8 West Front Street
Post Office Box 30
Media, Pennsylvania 19063
Telephone: (610) 565-0505
Facsimile: (610) 565-7315

ATTORNEYS FOR PLAINTIFFS
RUSSELL BRUESEWITZ and
ROBALEE BRUESEWITZ,
individually and on behalf
of their minor daughter,
HANNAH BRUESEWITZ

Date: June 18, 2007

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[9] Please note the change in firm name as of June 8, 2007.

PETITIONER'S BRIEF

Supreme Court
FILED
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No. 09-152

IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ,
PARENTS AND NATURAL GUARDIANS OF
HANNAH BRUESEWITZ, A MINOR CHILD,
AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES,
WYETH-AYERST LABORATORIES, WYETH LEDERLE,
WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Third Circuit

BRIEF FOR PETITIONERS

JOHN EDDIE WILLIAMS
JOHN T. BOUNDAS
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway
Suite 600
Houston, Texas 77017-5051
(713) 230-2200

COLLYN A. PEDDIE
THE LAW OFFICES OF
COLLYN PEDDIE
440 Louisiana, Suite 1710
Houston, Texas 77002-1689
(713) 422-1205

DAVID C. FREDERICK
Counsel of Record
DEREK T. HO
BRENDAN J. CRIMMINS
JANIE N. KUCERA
KELLOGG, HUBER, HANSEN,
TODD, EVANS & FIGEL,
P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

May 24, 2010

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 precludes liability for certain claims against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

The question presented is:

Does § 22(b)(1) preclude all vaccine design-defect claims even if the vaccine's side effects were avoidable?

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INTRODUCTION

Congress enacted the National Childhood Vaccine Injury Act ("NCVIA") in 1986 and 1987 against a long tradition of state-law design-defect claims against manufacturers for vaccines' injurious side effects. In reaching a historic compromise between vaccine makers seeking complete immunity from design-defect suits and families of victims whose lives had been irretrievably damaged by harmful vaccine side effects, Congress enacted numerous protections for both. Among them was a provision precluding liability for design defects in vaccines "if the injury or death resulted from side effects that *were unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (emphasis added).

In April 1992, petitioners Russell and Robalee Bruesewitz experienced one of a parent's worst nightmares when their healthy six-month-old daughter Hannah was injected with respondent Wyeth's Tri-Immunol diphtheria-tetanus-pertussis ("DTP") vaccine. Hannah immediately suffered scores of seizures and has been developmentally impaired ever since. Tri-Immunol, developed in the 1940s, had long been superseded by a more modern design, but Wyeth declined to change its DTP vaccine's design because it viewed the economic costs as outweighing any potential gain in market share. In 1998, Wyeth withdrew Tri-Immunol from the market.

This case presents the question whether the NCVIA categorically precludes all design-defect claims even if the vaccine's side effects were avoidable. The NCVIA's text, the statute's structure, the legislative history, and sound policy all confirm that

Congress intended to foreclose liability only when the harms caused by the vaccine's design were unavoidable, provided that the vaccine had been properly prepared and the warnings were adequate. Congress did not declare all vaccine side effects unavoidable as a matter of law, and it therefore did not preclude claims, like the Bruesewitzes', based on injuries caused by a scientifically outmoded design.

OPINIONS BELOW

The court of appeals' opinion (App.[1] A1-A52) is reported at 561 F.3d 233. The district court's opinion (App. A53-A100) is reported at 508 F. Supp. 2d 430.

JURISDICTION

The court of appeals entered its judgment on March 27, 2009, and denied rehearing on May 6, 2009 (App. A101-A102). The petition for a writ of certiorari was filed on August 4, 2009, and was granted on March 8, 2010 (130 S. Ct. 1734). This Court's jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 22 of the NCVIA, 42 U.S.C. § 300aa-22, is reproduced at App. A104-A106.

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[1] References to "App." are to the petition appendix.

STATEMENT

A. Statutory And Regulatory Background

1. The history of vaccine regulation

Vaccines consist of potent and potentially deadly pathogens administered to healthy individuals to stimulate the production of immunizing anti-bodies. *See Toner v. Lederle Labs.*, 779 F.2d 1429, 1430 (9th Cir. 1986) (Kennedy, J.). The whole-cell pertussis vaccine administered to Hannah Bruesewitz in 1992 consisted of "whole killed pertussis organisms" and was known by respondent to be "neurotoxic" "as early as the 1950's." *Id.* at 1430-31. Less dangerous "acellular" or "split-cell" versions of the DTP vaccine had been marketed in the United States and abroad by the 1960s, but Wyeth did not pull its whole-cell version from the market until 1998.

Because of their potential safety risks, vaccines historically have been regulated by states pursuant to their traditional police powers. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11, 38-39 (1905). Congress recognized as much when, in 1813, it initiated a short-lived and unsuccessful effort to regulate vaccines. *See* Act of Feb. 27, 1813, ch. 37, 2 Stat. 806. Enacted amid concerns over contaminated or fraudulent doses of smallpox vaccine, the 1813 Act authorized the President to appoint an agent to preserve and distribute "genuine vaccine matter." *Id.* § 1, 2 Stat. 806. In 1822, Congress repealed the law, *see* Act of May 4, 1822, ch. 50, 3 Stat. 677, concluding that vaccination was "not properly within the province of this Government but of the several States," 39 Annals of Cong. 1634 (1822).

From 1822 until early in the 20th century, state and local governments exercised exclusive authority over vaccination. *See, e.g.*, An Act for the Free

Distribution of Genuine Vaccine Matter, 1814 Va. Acts ch. 14, p. 43 (allocating funds for vaccinations); *State v. Hay*, 35 S.E. 459, 461 (N.C. 1900) (noting that the "power of the legislature to authorize county and municipal authorities to require compulsory vaccination has been exercised by nearly every state"). State courts also routinely adjudicated vaccine-related claims under state law.[2]

In 1902, Congress enacted the Biologics Control Act, ch. 1378, 32 Stat. 728. That legislation required any establishment preparing vaccines to obtain a license from the Treasury Secretary. *Id.* § 1, 32 Stat. 728. But it did not displace the primacy of state regulation: in the ensuing decades, state courts regularly adjudicated common-law claims brought by individuals injured by vaccines. Those included claims that manufacturers acted negligently in manufacturing vaccines, *see Baudenbach v. Schwerdtfeger*, 230 N.Y.S. 640 (N.Y. App. Div. 1928); in providing inadequate warnings, *see Carmen v. Eli Lilly & Co.*, 32 N.E.2d 729 (Ind. Ct. App. 1941); and in furnishing for inoculation vaccines that were "not sterile, safe, or suitable for the use for which [they were] intended," *Tremaine v. H.K. Mulford Co.*, 176 A. 212, 212-13 (Pa. 1935).

In 1944, Congress revised and recodified the 1902 law in the Public Health Service Act, ch. 373, 58 Stat. 682 ("PHSA") (codified as amended at 42 U.S.C. § 201 *et seq.*). The PHSA required manufacturers to

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[2] *See Hazen v. Strong*, 2 Vt. 427 (1830); *Abeel v. Clark*, 24 P. 383 (Cal. 1890); *Bissell v. Davison*, 32 A. 348 (Conn. 1894); *Duffield v. School Dist. of Williamsport*, 29 A. 742 (Pa. 1894); *Morris v. City of Columbus*, 30 S.E. 850 (Ga. 1898); *Wyatt v. City of Rome*, 31 S.E. 188 (Ga. 1898); *Blue v. Beach*, 56 N.E. 89 (Ind. 1900).

procure both an establishment and a product license before commercially distributing a vaccine. *Id.* § 351(a), 58 Stat. 702. Those licenses were granted if manufacturers met standards "designed to insure the continued safety, purity, and potency." *Id.* § 351(d), 58 Stat. 702. Although Congress has revised the PHSA and consolidated the two licenses into a single biologics license, *see* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 123(a)(2), (g), 111 Stat. 2296, 2323-24 ("1997 FDA Act"), the applicable statutory criteria by which vaccines are approved remain unchanged, *see* 42 U.S.C. § 262. The PHSA continues to be the primary source of authority for the federal regulation of vaccines, supplemented by various provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*

Passage of the PHSA in 1944 did not disturb state law's traditional role in providing compensation to individuals injured by vaccines. Many such claims continued to sound in negligence. *See, e.g.*, *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991, 994 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969); *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977). Courts also permitted strict-liability claims by victims seeking to recover even absent negligence. *See, e.g.*, *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968); *cf. Gottsdanker v. Cutter Labs.*, 6 Cal. Rptr. 320 (Cal. Ct. App. 1960). Notwithstanding federal regulatory efforts under the PHSA, courts routinely rejected claims that federal regulation of vaccines preempted state tort actions. *See Hurley v. Lederle Labs.*, 863 F.2d 1173, 1176 & n.2 (5th Cir. 1988) (citing cases). Thus, by the latter half of the 20th century, state law had developed a robust

corpus of case law establishing principles of manufacturer liability for vaccine injuries.

2. FDA regulation of vaccines

Since 1972, the Food and Drug Administration ("FDA") has also regulated vaccines and other biologics. *See* 37 Fed. Reg. 12,865 (June 29, 1972). FDA evaluation of a potential new vaccine begins when a sponsor approaches the agency with a product design and requests, via an Investigational New Drug application, authorization to conduct clinical trials. *See* 21 C.F.R. §§ 312.2(a), 312.20-312.38. Such trials aim to gather information about the safety and efficacy of the product in humans. *See id.*

Once clinical trials approach completion and the sponsor believes it has accumulated sufficient data concerning the vaccine's effect in humans, the sponsor may submit an application for a biologics license. *See id.* § 601.2. The sponsor must prove, *inter alia*, that the vaccine is safe, pure, potent, and effective. *See* 42 U.S.C. § 262; FDA, *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 4 (May 1998) ("FDA Guidance"), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM078749.pdf.

FDA defines "safety" as

> relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

21 C.F.R. § 600.3(p).

To demonstrate the vaccine's "safety" under FDA's regulations, the sponsor need not show that it has

adopted the safest feasible design, and FDA does not purport to ensure that drugs are optimally designed.[3] In that respect, FDA is a "passive agency," because "it considers whether to approve vaccine designs only if and when manufacturers come forward with a proposal." *Hurley*, 863 F.2d at 1177; *see also Jones by Jones v. Lederle Labs.*, 695 F. Supp. 700, 711 (E.D.N.Y. 1988) ("[T]he agency takes the drugs and manufacturers as it finds them. While its goal is to oversee inoculation with the best possible vaccine, it is limited to reviewing only those drugs submitted by various manufacturers, regardless of their flaws.").[4]

Once approved, a vaccine's formulation or manufacturing process need not remain static. Rather, any aspect of a vaccine—including design—may be changed on the manufacturer's initiative so long as certain regulations are followed. Before distributing a product incorporating a change, the manufacturer

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[3] *See* Thuy D. Pham & Annette P. Martinez, *The Polio Vaccine and the Restatement (Third) of Torts: Why the Controversies?*, 11 DePaul J. Health Care L. 125, 158-59 (2008) ("[T]he FDA is not per se involved in initiating or conceptualizing . . . vaccine design, nor does the agency actively test for optimum drug design."); George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 Yale L.J. 1087, 1128-29 (2000) ("FDA does not claim to review products for optimal design.").

[4] FDA's review of vaccine design is no more comprehensive than for other drug products. Many of the same provisions govern both approval processes, *see, e.g.*, 21 C.F.R. § 312.2(a), and FDA issues Guidance Documents concerning approval standards that govern biologics and drug products, *see, e.g.*, FDA Guidance at 4. In 1997, Congress instructed the Secretary of Health and Human Services ("HHS") to "take measures to minimize differences in the review and approval of [biologics and drug] products." 1997 FDA Act § 123(f), 111 Stat. 2324 (codified at 21 U.S.C. § 355 note).

must assess the impact of the change on the safety and effectiveness of the vaccine. *See* 21 C.F.R. § 601.12. Changes that have a "substantial potential" to affect safety and effectiveness require FDA approval, whereas changes with a "moderate potential" must be submitted to FDA 30 days before implementation to provide the agency an opportunity to require approval. *Id.* § 601.12(b)-(c). Other changes need only be described in an annual report to FDA. *Id.* § 601.12(d).

As FDA has acknowledged, because the number of people exposed to a vaccine during clinical trials is relatively small, harmful side effects often are discovered only after the vaccine is licensed and administered to the general public.[5] FDA has only limited tools for monitoring such developments. One is to condition approval of a vaccine on a manufacturer's commitment to undertake post-marketing studies, or so-called "Phase IV" studies. *See* 21 U.S.C. § 355(*o*)(3); 42 U.S.C. § 262(a)(2)(D), (j); 21 C.F.R. § 601.70. A recent Office of Inspector General review of these studies in the drug context, however, revealed that one-third of the manufacturers' annual status reports were incomplete; even complete reports lacked information that would be useful; and "[m]onitoring postmarketing study commitments is not a top priority at FDA."[6]

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[5] *See* http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicsLicenseApplicationsBLAProcess/ucm133096.htm ("Until a vaccine is given to the general population, all potential adverse events cannot be anticipated."); http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/history.html.

[6] Office of Inspector General, U.S. Dep't of Health & Human Servs., *FDA's Monitoring of Postmarketing Study Commitments*

FDA also conducts limited postmarketing surveillance of adverse events associated with vaccines. In doing so, however, "the Agency relies principally on a ***passive*** adverse event reporting system" that "depend[s] to a great extent on voluntary reporting by the healthcare community."[7] Although manufacturers and health care providers are required to report certain information about adverse events to FDA and a nationwide database known as the Vaccine Adverse Event Reporting System ("VAERS"), FDA has acknowledged that "[p]assive surveillance systems such as VAERS are subject to limitations" because "[v]accine-associated adverse events will inevitably be underreported to an unknown extent." 70 Fed. Reg. 75,180, 75,190 (Dec. 19, 2005). Moreover, FDA does not receive reports about safer alternatives, nor does it have authority to order a manufacturer to adopt a safer alternative design for a licensed vaccine. *See* 21 C.F.R. § 601.5.

3. The NCVIA

In the early 1980s, victims of vaccine-related injuries raised concerns about the cost, speed, and inconsistency of the tort system. *See* H.R. Rep. No. 99-908, pt. 1, at 6 (1986) ("1986 Report"), *reprinted in* 1986 U.S.C.C.A.N. 6344. At the same time, some vaccine manufacturers sought immunity from liability for vaccine-related injuries and deaths. *See id.* Congress considered numerous proposals for legisla-

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ii-iii (June 2006), *available at* http://oig.hhs.gov/oei/reports/oei-01-04-00390.pdf.

[7] Task Force on Risk Mgmt., U.S. Dep't of Health & Human Servs., *Managing the Risks from Medical Product Use: Creating a Risk Management Framework* 12 (May 1999), *available at* http://www.fda.gov/downloads/Safety/SafetyofSpecificProducts/UCM180520.pdf.

tion. One early bill contemplated a voluntary compensation program that preserved state-law rights without modification. *See* H.R. 5810, 98th Cong. § 2101 (1984). Other proposals, championed by the vaccine industry, severely limited the availability of state-law remedies. The House considered a proposal immunizing manufacturers from most claims of strict liability, *see* H.R. 5184, 99th Cong. § 2122(c)(1) (1986), and the Senate considered granting complete immunity to manufacturers of vaccines that had been "tested, manufactured, distributed, and labeled in accordance with [FDA] requirements," *National Childhood Vaccine Injury Compensation Act of 1985 (Part 2): Hearing on S.827 Before the S. Comm. on Labor & Human Resources*, 99th Cong. 16 (1985). Ultimately, Congress rejected those proposals in favor of a compromise approach.

The 1986 legislation. Congress enacted the NCVIA in 1986. *See* Pub. L. No. 99-660, tit. III, 100 Stat. 3743, 3755 (codified as amended at 42 U.S.C. § 300aa-1 *et seq.*). The Act created a no-fault administrative compensation program—the National Vaccine Injury Compensation Program ("Compensation Program")—to supplement the traditional tort system. Congress believed that the Program would provide compensation to victims of vaccine side effects "quickly, easily, and with certainty and generosity," 1986 Report at 3, and thereby "dissuade [victims] from going on to court," H.R. Rep. No. 100-391, pt. 1, at 691 (1987) ("1987 Report"), *reprinted in* 1987 U.S.C.C.A.N. 2313-1.

Congress placed the Compensation Program within a division of the U.S. Court of Federal Claims, colloquially termed "Vaccine Court." *See* 42 U.S.C. § 300aa-12. A claimant seeking more than $1,000 in

damages from a vaccine-related injury or death must submit a petition for compensation with the Vaccine Court before filing a civil action in state or federal court. *See id.* §§ 300aa-11, 300aa-21. A special master considers the petition in an administrative (rather than an adversarial) setting, with subsequent review by the Court of Federal Claims and then the Federal Circuit. *See id.* § 300aa-12(d)-(f).

The Compensation Program applies only to vaccines recommended by CDC for routine administration to children. *See id.* §§ 300aa-11(b), 300aa-14. Covered vaccines are listed in a Vaccine Injury Table maintained by HHS. *See id.* § 300aa-14; 42 C.F.R. § 100.3. The Table also lists selected injuries known to be associated with each vaccine and time limits for the onset of the injuries. *See* 42 U.S.C. § 300aa-14. A claimant who shows by a preponderance of the evidence that he sustained or the vaccine aggravated a listed injury within the specified timeframe (a so-called "Table injury") is presumptively entitled to compensation. *See id.* §§ 300aa-11(c), 300aa-13(a). A claimant who suffered a non-Table injury must show that the vaccine in fact caused the injury. *See id.* A claimant cannot receive compensation, however, if the court finds that the injury was caused by factors unrelated to administration of the vaccine. *See id.* § 300aa-13(a).

Although claimants must begin with a petition to the Vaccine Court, NCVIA § 21 permits victims to bring a "*de novo*" civil action if either of two conditions is satisfied. *Shalala v. Whitecotton*, 514 U.S. 268, 270 (1995). First, a claimant dissatisfied with the special master's decision may elect to decline the award and file a civil action. *See* 42 U.S.C. § 300aa-21(a). Second, if the special master fails to render a

decision within 240 days, the victim may withdraw the petition and proceed with a civil suit. *See id.* § 300aa-21(b)(1), (c). Congress designed the Compensation Program to be an "appealing alternative" to, but not a substitute for, the traditional tort system. 1986 Report at 26; *see Schafer v. American Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.).

Section 22 sets forth "standards of responsibility" to govern civil actions against vaccine manufacturers. 42 U.S.C. § 300aa-22(d); *see id.* § 300aa-23(b)-(d) (referring to determinations of liability "under section 300aa-22"). Subject to three narrow exceptions, the "[g]eneral rule" is that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." *Id.* § 300aa-22(a). Section 22(b)(1) provides one of those exceptions:

> **(b) Unavoidable adverse side effects; warnings**
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

Id. § 300aa-22(b)(1). Section 22(b)(2) then specifies that, "[f]or purposes of paragraph (1)," a vaccine ordinarily "shall be presumed to be accompanied by proper directions and warnings" if the manufacturer proves it complied with federal statutory and regula-

tory requirements. *Id.* § 300aa-22(b)(2).[8] Finally, § 22(e) ("Preemption") prohibits states from foreclosing civil actions against vaccine manufacturers if such actions are "not barred by this part." *Id.* § 300aa-22(e).

Section 22(b)(1) codifies comment k to § 402A of the Restatement (Second) of Torts (1965) ("Restatement"). *See, e.g.*, 1986 Report at 25 (explaining that the provision that became § 22(b)(1) "sets forth the principle contained in" comment k); 1987 Report at 691 (referring to "codification of Comment (k)"). Comment k carves out an exception to § 402A's strict products-liability rule for certain products that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement § 402A cmt. k. It provides that "[t]he seller of such products, . . . with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use." *Id.*

The NCVIA also prescribes a three-stage procedure by which civil actions for vaccine-related injuries must proceed. First, the court determines whether the "vaccine manufacturer is liable under [§ 22]." 42 U.S.C. § 300aa-23(b). The court next determines compensatory and then punitive damages. *See id.* § 300aa-23(c), (d)(1). The Act precludes punitive damages when the manufacturer can demonstrate compliance with applicable federal law. *See id.* § 300aa-23(d)(2).

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[8] Section 22(c) also precludes liability for failure to provide direct warnings to the vaccine recipient. 42 U.S.C. § 300aa-22(c).

The NCVIA's liability provisions reflected a carefully crafted compromise among the interests of victims and manufacturers. Congress did not enact funding for the Compensation Program before the end of the 99th Congress, however. Instead, Congress inserted an unusual provision that the NCVIA would not be effective unless and until Congress enacted further legislation providing funding for the Compensation Program. *See* NCVIA § 323(a), 100 Stat. 3784. Members who voted on the bill did so upon an express understanding that it would have no effect until further legislation was considered in the next Congress. *See, e.g.*, 132 Cong. Rec. 30,751, 30,761 (1986) (statement of Rep. Frenzel). Likewise, in signing the Act into law, President Reagan expressed "serious reservations" and enumerated numerous "corrective program changes" he wished to see before the legislation became effective.[9]

The 1987 legislation. When funding of the NCVIA was taken up in 1987, many lawmakers and interest groups attempted to revise the Act. The Reagan Administration expressed disappointment that the Compensation Program "would merely represent an alternative and in many cases preliminary forum to the tort system" and that "[a] showing by the manufacturer that it had complied with all material Federal regulatory requirements . . . would not give rise to a presumption that the vaccine was not defective in design."[10] Vaccine manufacturers

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[9] President Ronald Reagan, Statement on Signing the State Comprehensive Mental Health Plan Bill (Nov. 14, 1986), *available at* http://www.presidency.ucsb.edu/ws/print.php?pid=36733.

[10] *Funding of the Childhood Vaccine Program: Hearing Before the Subcomm. on Select Revenue Measures of the H. Comm. on*

expressed similar reservations and likewise advocated revisiting some of the Act's central provisions. *See* 1987 Hearing at 82, 84, 85, 102.

Fearing the compromises negotiated the year before would unravel, groups representing the families of injured victims insisted that "[t]he new funding law . . . not tamper with existing safeguards of [the NCVIA], . . . includ[ing]: preservation of parents' right to sue vaccine makers . . . in cases involving negligence [or] unreasonably dangerous vaccines." *Id.* at 64.

Ultimately, Congress passed legislation funding the Compensation Program through an excise tax on each vaccine dose. *See* Vaccine Compensation Amendments of 1987, Pub. L. No. 100-203, tit. IV, subtit. D, 101 Stat. 1330, 1330-221; 42 U.S.C. § 300aa-15(i)(2); 26 U.S.C. §§ 4131-4132, 9510. While the 1987 legislation modified the NCVIA's substantive provisions in several respects,[11] Congress left the provisions relating to civil actions against vaccine manufacturers intact. The Committee Report accompanying the 1987 legislation confirmed that

> [i]t is not the Committee's intention to preclude court actions under applicable law. The Committee's intent at the time of considering the Act and in these amendments was and is to leave otherwise applicable law unaffected, except as expressly altered by the Act and the amendments.

Ways and Means, 100th Cong. 18, 25 n.7 (1987) ("1987 Hearing") (statement of Dennis E. Ross, Tax Legislative Counsel, Treasury Department).

[11] For example, Congress transferred jurisdiction over the Compensation Program from the federal district courts to the U.S. Court of Federal Claims. *Compare* NCVIA § 311(a), 100 Stat. 3761, *with* 42 U.S.C. § 300aa-12.

> An amendment to establish as part of this compensation system that a manufacturer's failure to develop safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act. Further, the codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

1987 Report at 691.

B. The History Of The DTP Vaccine

Pertussis, commonly known as "whooping cough," is a bacterial respiratory infection caused by the bacterium *B. pertussis*. *See* Stefania Salmaso, *Pertussis*, *in The Vaccine Book* 211, 212 (Barry R. Bloom & Paul-Henri Lambert eds., 2003) ("Salmaso"). The first pertussis vaccine was approved by the federal government in 1914. *See* Kathyrn M. Edwards & Michael D. Decker, *Pertussis vaccines*, *in Vaccines* 467, 479 (Stanley A. Plotkin, Walter A. Orenstein & Paul A. Offit eds., 5th ed. 2008) ("Edwards & Decker"). That original vaccine was a "whole cell" pertussis vaccine because it consisted of a suspension of inactivated whole *B. pertussis* cells. *See id.* By the 1940s, the whole-cell vaccine was commonly combined with diphtheria and tetanus toxoids to form the DTP vaccine. *See id.* The Wyeth Tri-Immunol vaccine administered to Hannah Bruesewitz was a

whole-cell vaccine initially licensed in the 1940s. *See* JA134-35 (detailing Tri-Immunol's licensing history).

The whole-cell pertussis vaccine has "long been recognized as one of [the] most reactogenic vaccines," causing adverse reactions that include acute encephalopathy, anaphylaxis, and febrile seizures. Edwards & Decker at 485-87; *accord Toner*, 779 F.2d at 1430. Concerns about the vaccine's safety were raised as early as the 1930s; by the late 1940s, two widely cited articles confirmed the vaccine's neurotoxic effect.[12] Lederle Laboratories ("Lederele"), which Wyeth acquired in 1994, "was aware of the neurotoxicity of Tri-Immunol as early as the 1950's." *Id.* at 1431. Criticism of the vaccine's safety increased over the next several decades and prompted action abroad: in 1979, Sweden withdrew use of the whole-cell pertussis vaccine, and Japan abandoned the vaccine in favor of an acellular version in 1981.[13]

The whole-cell vaccine's toxicity prompted scientists to research a less harmful pertussis vaccine. In the 1950s, researchers published a methodology for producing a less toxic vaccine, and, by the 1960s, Eli Lilly had obtained approval from the federal

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[12] *See* Thorvald Madsen, *Vaccination Against Whooping Cough*, 101 J. Am. Med. Ass'n 187 (1933); Louis W. Sauer, *Whooping Cough: A Study in Immunization*, 100 J. Am. Med. Ass'n 239 (1933); Randolph K. Byers & Frederic C. Moll, *Encephalopathies Following Prophylactic Pertussis Vaccine*, 14 Pediatrics 437 (1948); John A. Toomey, *Reactions to Pertussis Vaccine*, 139 J. Am. Med. Ass'n 448 (1948).

[13] *See* Elizabeth Miller, *Progress Towards A New Pertussis Vaccine*, 292 British Med. J. (Clinical Research Edition) 1348, 1348-49 (May 24, 1986).

government to distribute a split-cell vaccine.[14] The vaccine, sold under the trade-name Tri-Solgen, dominated the market because it was "superior" to whole-cell forms. *See* JA245 (internal correspondence noting that Eli Lilly has "half of [the market] because of a superior product"); JA208 (internal correspondence noting that "Eli Lilly[] has successfully developed a non-cellular pertussis vaccine" and "has swung the triple vaccine . . . market in their favor").

In the late 1960s, Lederle conducted internal studies confirming that its whole-cell Tri-Immunol was more reactogenic than Eli Lilly's split-cell Tri-Solgen. *See* JA230-34 (internal correspondence noting "significant differences in reaction rates were observed in infants receiving either Lederle Tri-Immunol or Lilly Tri Solgen"); JA66; Burke, 17 Seton Hall L. Rev. at 569. Lederle's internal correspondence shows that the company tried briefly in the late 1960s to create "an improved pertussis component," but "[d]rop[ped]" the project after concluding that "[t]he effort is not worth it for the total market." JA242; *see* JA245 ("The effort [to develop an acellular version] is certainly not commensurate with the gain.").

In the mid-1970s, Eli Lilly stopped producing Tri-Solgen. Wyeth obtained the right to produce the vaccine, but chose to reformulate the product. *See Graham by Graham v. Wyeth Labs.*, 906 F.2d 1399, 1403 (10th Cir. 1990). Despite the reformulation, Wyeth wanted to keep the Tri-Solgen trade name. *See* JA204-05. FDA denied Wyeth permission to do

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[14] *See* James M. Burke, *DPT Vaccine Controversy: An Assessment of the Liabilities of Manufacturers and Administering Physicians Under Several Legal Theories*, 17 Seton Hall L. Rev. 541, 569 (1987).

so, noting that it might constitute "mislabeling." *Id.* Wyeth never marketed the original formulation of Tri-Solgen and, for the next two decades, Tri-Immunol remained on the market. *See generally* Burke, 17 Seton Hall L. Rev. at 569-70, 573-75.

In 1998—six years after Hannah Bruesewitz received the injection that caused her injuries—Wyeth ceased production of Tri-Immunol. *See* JA135. By that point, it had applied for, and received, a biologics license for "DTaP" vaccine that incorporated an acellular pertussis component. Marketed under the trade name Acel-Imune, the vaccine was approved for use in fourth and fifth doses of childhood vaccination series in December 1991 and for all doses in 1996. *See* JA36. The pertussis component of Acel-Imune is sourced from Japan, where manufacturers have been producing and marketing acellular pertussis vaccines since the 1970s. *See* CDC, *Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among Infants and Young Children*, Morbidity and Mortality Weekly Report, Vol. 46, No. RR-7, at 3 (Mar. 28, 1997), *available at* http://www.cdc.gov/mmwr/PDF/rr/rr4607.pdf. CDC's studies have shown that the acellular pertussis vaccine has comparable efficacy but is associated with fewer adverse events than the whole-cell version. *See id.* at 4; Salmaso at 218, 220. The whole-cell pertussis vaccine is no longer marketed in the United States, Canada, Australia, and several Asian and European countries.

C. Administration Of Wyeth's DTP Vaccine To Hannah Bruesewitz

On April 1, 1992, Hannah Bruesewitz, then a healthy six-month-old baby girl, received her third dose of Wyeth's Tri-Immunol vaccine. *See* App. A6. Within hours, Hannah experienced her first seizure.

See Bruesewitz v. Secretary of HHS, No. 95-0266V, 2002 WL 31965744, at *2 (Fed. Cl. Dec. 20, 2002). Over the next 16 days, Hannah experienced a total of 125 seizures, at times spaced at one every half hour. *See id.* at *2-*4.

Over the ensuing months, Hannah's symptoms progressively worsened. Her medical records note that she was lethargic, exhibited autistic-like features, and was developmentally delayed. *See id.* at *4-*5. At 20 months, she had no discernible speech and comprehended only simple commands. *See id.* at *6. Of eight electroencephalograms ("EEGs") taken between April 1992 and July 1995, seven were abnormal, and a CT scan taken at the end of that period showed diffuse neuronal loss. *See id.* at *5-*7. In the four years that followed her vaccination, Hannah was prescribed numerous medications to treat her symptoms, including Felbatol, which is prescribed for severe epilepsy. *See id.* at *4-*6; JA124; http://www.felbatol.com/felbatol.html.

A neurobehavioral evaluation in 2003 diagnosed Hannah with "pervasive developmental disorder and seizure disorder" and recommended her continued involvement in "intensive high-quality one-on-one intervention," as well as occupational and speech therapy. JA126-27. Now a teenager, Hannah suffers from residual seizure disorder and remains developmentally impaired. She will require a lifetime of supervision and care.

The vaccine dose Hannah received came from a lot associated with an unusually large number of adverse events. By the time of her inoculation, VAERS reported 1 death and 30 adverse events, including 8 reports of convulsions, from the lot; those numbers later rose to 2 deaths and more than 60

adverse events (including 39 emergency room visits). *See* JA202-03. Wyeth and Lederle apparently took deliberate steps to obscure adverse events associated with particular lots of vaccine. Internal correspondence in the 1970s suggested that the company report adverse events individually rather than in a summary fashion, stating that "[w]e would not want several cases in a summary [to] be discovered by Plaintiff's counsel." JA267; *see also* JA252-53. Another internal memorandum was written after eight children in Tennessee died within one week of receiving the DTP vaccine. *See* JA268-69; *see also* JA252-53. It noted that, after the incident, senior management agreed to "limit[] distribution of a large number of vials from a single lot to a single state, county or city health department." JA268. Hannah's physician testified that she would not have administered the particular vaccine dose to Hannah had she known that it came from a lot associated with such a large number of adverse events. *See* JA203.

D. Proceedings Below

1. On April 3, 1995, the Bruesewitzes filed a petition in the Vaccine Court, seeking compensation under the NCVIA for their daughter's injuries. *See* JA1. Just one month before her petition was filed, new regulations eliminated "residual seizure disorder" from the Vaccine Table for DTP. *See Bruesewitz*, 2002 WL 31965744, at *1 n.1. In December 2003, the court dismissed the petition with prejudice after concluding that Hannah suffered only non-Table injuries and had not proved that the DTP vaccine caused her injuries. *Id.* at *17; *but cf. Andreu ex rel. Andreu v. Secretary of HHS*, 569 F.3d 1367, 1374-75 (Fed. Cir. 2009) (reversing special master's finding that parents failed to show causal relation-

ship between whole-cell pertussis vaccine and son's seizures). On February 14, 2003, petitioners elected to reject the court's judgment under § 21. *See* JA2.

2. In October 2005, petitioners filed a complaint against Wyeth in Pennsylvania state court, seeking damages for Hannah's injuries under state law. *See* JA5-6. Wyeth removed the case on diversity grounds to federal district court. *See* JA6, 7. Petitioners' amended complaint alleged that Wyeth negligently failed to develop a safer vaccine and was strictly liable for injuries caused by the vaccine's defective design. *See* JA55-60.

Wyeth moved for summary judgment, arguing that NCVIA § 22(b)(1) expressly preempts liability based on defective design of FDA-approved childhood vaccines, irrespective of whether a safer alternative vaccine existed at the time of vaccination. Despite the district court's invitation to submit an *amicus* brief, FDA and HHS declined, stating that, "[a]fter careful review, HHS and FDA have determined that they do not have views on the issues presented." App. A107.

The court granted Wyeth's motion for summary judgment on petitioners' design-defect claims. The court acknowledged that § 22(b)(1) was "[i]nformed by" comment k of Restatement § 402A. App. A67. The court then analyzed comment k and determined that it

> suggests that the question of whether a particular vaccine is unavoidably unsafe—and therefore subject to the immunity from suit posited by comment k—is a question of fact for a jury to determine. That is, the trier of fact must decide whether the challenged vaccine is the only design available, "in the present state of human knowledge."

App. A83-A84. Notwithstanding those conclusions, the court held that "§ 22(b) is broader than comment k, so that the [NCVIA] preempts state law determinations of whether a vaccine is unavoidably unsafe, and therefore entitled to comment k immunity." App. A85.

3. The Third Circuit affirmed. That court concluded that § 22(b)(1) was an express preemption provision, although it was unable to "resolve from statutory text alone the scope of the express preemption provision." App. A21, A26. Instead, the court relied on § 22's "structure" and legislative history in concluding that it precludes all design-defect claims. App. A27.

First, the court relied heavily on § 22(e), which "prohibits states from foreclosing civil actions that are otherwise 'not barred by this part.'" App. A27-A28. It read that language as "stating that other parts of § 300aa-22 are designed to not only limit liability but bar some claims entirely." App. A28. On that basis, the court concluded that Congress could not have intended "case-by-case analysis of whether particular vaccine side effects are avoidable," because then "every design defect claim [would be] subject to evaluation by a court." App. A29. It thus rejected petitioners' interpretation of § 22(b) because it "does not bar *any* design defect claims." *Id.* (emphasis added). However, the court said it could not determine from structure alone whether § 22(b)(1) preempts all such claims, or only those sounding in strict liability. *See* App. A29, A31.

To resolve that issue, the Third Circuit reviewed the NCVIA's legislative history. In concluding that the Act precluded all design-defect claims, regardless of fault, the court relied on a 1986 House Energy

and Commerce Committee Report. *See* App. A31-A36. The court acknowledged that the report stated that the Act "reflected the principle of Restatement (Second) of Torts § 402A comment k." App. A33. It also recognized that a majority of courts have interpreted comment k as permitting a case-by-case analysis of whether a particular product is unavoidably unsafe. *See id.* However, the court viewed the following language as reflecting Congress's intent to eliminate all design-defect claims: "Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should [sic] pursue recompense in the compensation system, not the tort system." 1986 Report at 26. The court gave no weight to the statement in the Committee Report accompanying the 1987 legislation that whether a vaccine's side effects are "unavoidable" must be determined on a case-by-case basis. *See supra* pp. 15-16.[15]

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[15] The Third Circuit also suggested that, even if Congress did not preempt all design-defect claims, it preempted petitioners' specific claim regarding the safety of the whole-cell pertussis component of the DTP vaccine. *See* App. A40-A42.

SUMMARY OF ARGUMENT

I. Section 22(b)(1) of the NCVIA exempts vaccine manufacturers from civil liability for vaccine-related injuries only if those injuries resulted from unpreventable side effects. The clause "if the injury or death resulted from side effects that were unavoidable" commands that conclusion. The ordinary definition of the word "unavoidable" is "incapable of being . . . prevented." By 1986, "unavoidable" also had attained a well-accepted legal meaning derived from comment k to Restatement § 402A and confirmed by numerous state and federal courts: a product's safety risks are "unavoidable" only if it is "incapable of being made safe for [its] intended and ordinary use." Restatement § 402A cmt. k.

Congress's use of the conditional word "if" to introduce the clause incorporating "unavoidable" side effects makes clear that a manufacturer is eligible for the liability exemption under § 22(b)(1) only upon a threshold showing that the vaccine's side effects could not have been prevented. Consistent with comment k and the majority of cases interpreting it, § 22(b)(1)'s conditional language contains no legal determination or presumption that all vaccine side effects are "unavoidable," but instead requires manufacturers to make that showing in a particular case. Congress also used conditional language in § 22(b)(2) and § 23(d)(2), which likewise require case-specific determinations. In contrast, when Congress wanted to create a categorical defense to liability for vaccine manufacturers, it did so explicitly without conditional language.

The clause "even though the vaccine was properly prepared and was accompanied by proper directions and warnings" is best read to impose comment k's

two *additional* prerequisites to exemption from liability, namely, that the vaccine be properly manufactured and accompanied by proper directions and warnings. The "even though" clause modifies the clause "if the injury or death resulted from side effects that were unavoidable," rather than just the word "unavoidable," thereby establishing proper manufacturing and proper directions and warnings as additional requirements. Given Congress's clear intent to codify comment k, that reading appropriately harmonizes § 22(b)(1) with comment k's standards, rather than eliminating comment k's core prerequisite that a vaccine be "unavoidably" unsafe. That reading also comports with the presumption against preemption.

II. The NCVIA's legislative history confirms that § 22(b)(1) does not exempt vaccine manufacturers from liability for preventable injuries. The Act's congressional sponsors, the President, and vaccine manufacturers all understood that manufacturers would remain responsible for making their vaccines as safe as possible for patients. Indeed, before the 1986 Act was passed, and then again before the 1987 legislation was enacted, industry representatives—including respondent Lederle's president—expressed dissatisfaction that § 22(b) did *not* immunize manufacturers from suits alleging that side effects could have been prevented by a safer design and urged Congress to enact a blanket immunity from design-related liability for vaccines approved by FDA. But Congress refused to do so. Instead, in enacting the 1987 funding legislation that put the NCVIA into effect, the Energy and Commerce Committee "stresse[d] that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably

unsafe or not. This question is left to the courts to determine in accordance with applicable law." 1987 Report at 691.

III. Interpreting § 22(b)(1) to exempt manufacturers from liability only for unpreventable injuries promotes Congress's purposes of ensuring vaccine safety and providing compensation to innocent victims of vaccine injury. Allowing design-defect claims for preventable harms provides a critical incentive for vaccine manufacturers to conduct adequate research, design their vaccines as safely as possible, and incorporate scientific advances into vaccine design to protect the public from unnecessary harm. Private lawsuits also promote FDA's regulation of vaccines because they help to unearth information about adverse side effects that FDA does not require manufacturers to submit in the regulatory process.

In contrast, eliminating all design-defect claims would not only undermine these social benefits, but also limit fair compensation to children and families injured by unnecessarily harmful vaccines. Indeed, if the decision below is affirmed, injured children would be denied redress even for injuries caused by recklessly designed vaccines or vaccines that a manufacturer knew would cause unnecessary harm. No sound policy justifies such a result. Respondent's dire warnings that vaccine manufacturers will leave the market unless all design-related liability is eliminated lack empirical support, given the success of the Compensation Program in reducing injured parties' need to resort to the tort system, and, in all events, are contrary to the policy balance struck by Congress. Certainly no such fear is warranted here, where respondent voluntarily took the vaccine that caused Hannah Bruesewitz's injuries off the market and other, safer DTP vaccines existed.

ARGUMENT

I. SECTION 22(b) OF THE NCVIA DOES NOT PRECLUDE OR PREEMPT CLAIMS SEEKING COMPENSATION FOR PREVENTABLE VACCINE-RELATED INJURIES

A. Under § 22(b)(1), Manufacturers Are Exempted From Civil Liability Only If The Vaccine's Side Effects Are "Unavoidable"

Section 22(a) provides as a "[g]eneral rule" that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a). Congress expressly preserved state law as the rule of decision for claims by injured children and their families against vaccine manufacturers, subject only to three exceptions set forth in subsections (b), (c), and (e). The relevant exception here—§ 22(b)—creates a limited exemption from otherwise applicable civil liability under state law "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." *Id.* § 300aa-22(b)(1).

1. Congress's use of the term "unavoidable" exempts vaccine manufacturers from civil liability only if the vaccine's side effects could not have been prevented

In construing statutes, this Court "begin[s], as always, with the text of the statute." *Permanent Mission of India to United Nations v. City of New York*, 551 U.S. 193, 197 (2007); *accord BP Am. Prod. Co. v. Burton*, 549 U.S. 84, 91 (2006) ("We start, of course, with the statutory text."). Here, the plain meaning of the word "unavoidable" is "not avoidable," "incapable of being . . . prevented," or "inevitable." *Webster's Third New International Dictionary* 2483

(2002) ("*Webster's*"). Thus, the plain meaning of the clause "if the injury or death resulted from side effects that were unavoidable" is that manufacturers are immunized from civil liability only if the vaccine's side effects could not have been prevented. If the side effects could have been avoided by a safer design, the product is defective, and the manufacturer is subject to liability for the resulting injuries.

The plain meaning of the term "unavoidable" is bolstered by the term's well-accepted legal meaning in products liability law. The term "unavoidable" is not merely a "generic or descriptive term, but a legal term of art" derived from comment k to Restatement § 402A. *Hamling v. United States*, 418 U.S. 87, 118 (1974); *see Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 399 n.1 (6th Cir. 1990) ("The term 'unavoidably unsafe' is a term of art derived from the Restatement.").

Section 402A holds the seller of "any product in a defective condition unreasonably dangerous to the user or consumer" strictly liable for any injuries caused by the product, irrespective of whether the "seller has exercised all possible care in the preparation and sale of his product." Restatement § 402A(1)-(2); *see id.* cmt. a. Strict liability is justified because "the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it" and "the burden of accidental injuries caused by products intended for consumption [should] be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained." *Id.* cmt. c.

Comment k to § 402A creates an exemption from strict liability for "unavoidably unsafe products,"

which are defined as those that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.* cmt. k. Such products are not considered "defective" or "*unreasonably* dangerous," and therefore are exempt from strict liability, "notwithstanding the unavoidable high degree of risk which they involve." *Id.* Thus, in the Restatement's parlance, "unavoidable" describes the inherent risks attendant to certain products that, while socially useful, cannot be made safer given the limits of then-prevailing scientific knowledge. *See* Am. L. Prods. Liab. 3d § 17:36, at 17-69 (1997).

Numerous state and federal cases confirmed the settled meaning of the term "unavoidable" prior to the NCVIA's enactment. Those decisions consistently interpreted "unavoidably unsafe" to mean that the product is designed in a way that does not present unnecessary risks of harm.[16] By 1986, "unavoidable"

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[16] *See, e.g., Smith ex rel. Smith v. Wyeth Labs., Inc.*, No. Civ.A. 84-2002, 1986 WL 720792, at *5 (S.D. W. Va. Aug. 21, 1986) ("[A] prescription drug is not 'unavoidably unsafe' when its dangers can be eliminated through design changes that do not unduly affect its cost or utility."); *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463-64 (Cal. Ct. App. 1985) ("unavoidability" turns on "(i) whether the product was designed to minimize—to the extent scientifically knowable at the time it was distributed—the risk inherent in the product, and (ii) the availability . . . of any alternative product that would have as *effectively* accomplished the *full intended purpose* of the subject product"), *disapproved in part by Brown v. Superior Ct.*, 751 P.2d 470 (Cal. 1988); *Feldman v. Lederle Labs.*, 479 A.2d 374, 386 (N.J. 1984) ("unavoidability" turns, in part, on whether there were "other design alternatives within practical and technological limits at the time of distribution") (internal quotations omitted); *Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 122 (Colo. 1983) (for comment k to apply, a "product's benefits must not be achievable in another manner"); *Cassisi v. Maytag Co.*,

had acquired a specialized meaning: a product's safety risks are "unavoidable" only when they cannot be eliminated by a safer alternative design.

When Congress uses a term of art in a statute, it intends that term "to have its established meaning." *McDermott Int'l, Inc. v. Wilander*, 498 U.S. 337, 342 (1991). "[W]here Congress borrows terms of art . . . , it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed." *Morissette v. United States*, 342 U.S. 246, 263 (1952); *see also Buckhannon Bd. & Care Home, Inc. v. West Virginia Dep't of Health & Human Res.*, 532 U.S. 598, 615 (2001) ("Words that have acquired a specialized meaning in the legal context must be accorded their *legal* meaning.") (Scalia, J., concurring). That canon of statutory interpretation is dispositive here: Congress's use of the term "unavoidable" in § 22(b)(1) indicates that it did not eliminate all design-related claims against vaccine manufacturers; rather, it exempted manufacturers from liability only with respect to side effects that could not have been prevented by a safer design. *See Schafer*, 20 F.3d at 3 (NCVIA "forbids the award of compensation for injuries that flow from 'unavoidable side effects'").

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396 So. 2d 1140, 1145-46 (Fla. Dist. Ct. App. 1981) (whether a product is "unavoidably unsafe" largely depends on whether the product is defectively designed); *Racer v. Utterman*, 629 S.W.2d 387, 393 (Mo. Ct. App. 1981) (comment k applies only when a product is "designed as safely as human knowledge makes possible").

2. Section 22(b)(1)'s plain language makes exemption from civil liability conditional upon a case-specific showing that the side effects of the vaccine in question are "unavoidable"

a. By its plain terms, the clause "*if* the injury or death resulted from side effects that were unavoidable" means that, to come within the exemption set forth in § 22(b)(1), a manufacturer must show in a given case that the vaccine in question was, in fact, designed to minimize its inherent risks. The ordinary meaning of the word "if" is "in the event that," "so long as," or "on condition that." *Webster's* at 1124. Congress's use of the conditional tense expresses its clear intent to exempt vaccine manufacturers from civil liability only upon a showing that the vaccine at issue in the lawsuit was designed as safely as possible. *See American Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 240 (Ga. 2008) ("The conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable."), *petition for cert. pending*, No. 08-1120 (U.S. filed Mar. 5, 2009). Notably, nowhere did Congress expressly state or provide that *all* vaccines were unavoidably unsafe.

The plain language of § 22(b)(1) also is consistent with comment k, which Congress expressly codified. Whether a given product is, "in the present state of human knowledge," "incapable of being made safe for [its] intended and ordinary use" requires a case-specific analysis of the product's safety risks compared to available alternatives. Comment k confirms the case-specific nature of the "unavoidable" inquiry: although it recognized that unavoidably unsafe

products are "especially common in the field of drugs" and vaccines, and gave the Pasteur rabies vaccine as an "outstanding example" of such a product, it made clear that some drugs and vaccines might *not* qualify. Restatement § 402A cmt. k ("The same is true of *many other* drugs, vaccines, and the like .... It is also true in particular of *many* new or experimental drugs[.]") (emphases added); *see also id.* ("*some products* ... are quite incapable of being made safe") (emphasis added).

"The drafters of comment k did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability. Such an exception was proposed at the American Law Institute meeting where section 402A and comment k were adopted, but this proposal was defeated." *Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989). Comment k thus plainly requires, as a threshold matter, a determination that the specific product cannot be made safer within the limits of extant scientific and technological knowledge. A product that *can* be made safer would not qualify for the exemption from strict liability under comment k, and it likewise does not qualify for the exemption under § 22(b)(1). *See* Am. L. Prods. Liab. 3d § 17:36, at 17-67 ("Comment k is not intended to provide all ethical drugs with blanket immunity from strict liability design defect claims, but rather courts must decide the applicability of the doctrine on a case-by-case basis after considering evidence related to the various factors set forth in Comment k.").

Section 22(b)(1)'s plain language also is consistent with the weight of judicial authority interpreting comment k, both in 1986 and today. A majority of states in 1986 required manufacturers to make a

case-specific showing that the product was "unavoidably unsafe" in order to avoid strict products liability.[17] As the court below acknowledged (App. A33 n.9), the majority position favoring a case-by-case approach among state-court decisions has become even more dominant since 1986. *See* Am. L. Prods. Liab. 3d § 17:47, at 17-86 ("Most courts have stated that there is no justification for giving all prescription drug manufacturers blanket immunity from strict liability under Comment k, and that whether

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[17] *See, e.g., Ortho Pharm. Corp. v. Heath*, 722 P.2d 410 (Colo. 1986), *overruled on other grounds by Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992); *Smith ex rel. Smith*, 1986 WL 720792; *Kearl*, 218 Cal. Rptr. 453; *Coursen v. A.H. Robins Co.*, 764 F.2d 1329 (applying Oregon law), *opinion corrected*, 773 F.2d 1049 (9th Cir. 1985); *Feldman*, 479 A.2d 374; *Belle Bonfils*, 665 P.2d 118; *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981) (applying New Hampshire law); *see also Racer*, 629 S.W.2d 387; *Jackson v. Muhlenberg Hosp.*, 232 A.2d 879 (N.J. Super. Ct. Law Div. 1967), *rev'd and remanded on other grounds*, 249 A.2d 65 (N.J. 1969).

The Third Circuit erred when it suggested, relying exclusively on *Militrano ex rel. Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 844-45 (N.Y. Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006), that there was no majority rule in 1986. *See* App. A33 n.9. Of the four cases that *Militrano* cited in favor of a categorical approach, *Davis*, 399 F.2d at 128-30, actually adopted a case-by-case approach; a second contained no sustained discussion on the point, *see Christofferson v. Kaiser Found. Hosps.*, 92 Cal. Rptr. 825 (Cal. Ct. App. 1971); and a third was overruled before 1986, *see Lewis v. Baker*, 413 P.2d 400 (Or. 1966), *overruled by McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974). The fourth case was overruled after 1986. *See McDaniel v. McNeil Labs., Inc.*, 241 N.W.2d 822, 828-29 (Neb. 1976), *overruled by Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827 (Neb. 2000).

a particular drug is unavoidably unsafe should be determined on a case-by-case basis.").[18]

The clear, conditional language of § 22(b)(1), therefore, cannot plausibly be read categorically to exempt *all* vaccines from design-related liability. Congress would not have used the word "if" to introduce the ensuing clause had it intended to foreclose for adjudication the question whether a vaccine's side effects were, in a given case, "unavoidable." That conclusion also follows from the case-by-case inquiry that must be made to determine whether a particular vaccine's method of preparation and warnings are adequate. Structurally, it is implausible to suppose that Congress intended complete immunity for vaccine design defects but a case-by-case analysis of warnings and preparations.

b. Two other provisions of the NCVIA confirm that Congress required a case-specific threshold determination of whether a vaccine's design is unavoidably unsafe. In § 22(b)(2), Congress created a presumption that, for purposes of § 22(b)(1), "a vaccine shall be presumed to be accompanied by proper directions and warnings *if* the vaccine manufacturer shows that it complied in all material respects with" federal labeling requirements. 42 U.S.C. § 300aa-22(b)(2) (emphasis added). A manufacturer must show such compliance on a case-by-case basis; to find

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[18] *See Weiss v. Fujisawa Pharm. Co.*, Civil Action No. 5:05-527-JMH, 2006 WL 3533072, at *2-*3 & n.3 (E.D. Ky. Dec. 7, 2006) (collecting cases and noting majority position); *Freeman*, 618 N.W.2d at 840 (also acknowledging majority position); *see also, e.g., Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 924 (Kan. 1990); *Hill*, 884 F.2d at 1068-69; *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988); *Senn v. Merrell-Dow Pharms., Inc.*, 751 P.2d 215, 218 n.4 (Or. 1988); *Toner v. Lederle Labs.*, 732 P.2d 297, 309 (Idaho 1987).

all vaccines to have complied with federal regulations would read that provision out of the statute. Likewise, in § 23(d)(2), Congress created an exemption from punitive damages "*[i]f* . . . the manufacturer shows that it complied, in all material respects," with those same federal laws (unless it engages in "fraud," "intentional withholding of information" from federal regulators, or "other criminal or illegal activity"). *Id.* § 300aa-23(d)(2) (emphasis added). Again, compliance sufficient to avoid punitive damages can be ascertained only based on the facts of each case. Congress's use of "if" clauses to establish the conditional nature of those provisions reinforces the conclusion that § 22(b)(1) similarly requires a conditional, case-specific analysis.

Furthermore, Congress's omission of a regulatory compliance defense or presumption with respect to design-related liability makes clear that it left the question whether "the injury or death resulted from side effects that were unavoidable" to be adjudicated in each case. "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Brown v. Gardner*, 513 U.S. 115, 120 (1994) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)). That admonition is all the more fitting when the "disparate inclusion [and] exclusion" are within the same statutory section. In so doing, Congress entrusted judges with making individualized determinations.

When Congress intended to exempt manufacturers from design-related liability regardless of whether the side effects were avoidable, it did so explicitly. For example, Congress authorized the Secretary of

HHS to designate a vaccine designed to prevent a pandemic or epidemic as a "covered countermeasure." 42 U.S.C. § 247d-6d(b), (i)(1), (i)(7)(A)(i). A manufacturer of a covered countermeasure is generally "immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration" of the covered countermeasure, including claims relating to "the design" of the countermeasure. *Id.* §§ 247d-6d(a)(1), (2)(B).[19] Congress enacted no such categorical exemption here.

B. The Proviso "Even Though The Vaccine Was Properly Prepared And Was Accompanied By Proper Directions And Warnings" Is Properly Read As Establishing Two Additional Prerequisites To Exemption From Civil Liability

Under comment k, a manufacturer is exempt from strict liability only if its products, in addition to being unavoidably unsafe, "are properly prepared and marketed, and proper warning is given." Restatement § 402A cmt. k; *see also id.* ("Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous."); Am. L. Prods. Liab. 3d § 17:36, at 17-69. Reading the clause "even though the vaccine was properly prepared and was accompanied by proper directions and warnings" to incorporate those

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[19] During the 1970s swine flu pandemic, Congress provided that "[t]he remedy against the United States . . . for personal injury or death arising out of the administration of the swine flu vaccine under the swine flu program shall be exclusive of any other civil action or proceeding for such personal injury or death." 42 U.S.C. § 247b(k)(3) (Supp. I 1977) (repealed 1979).

additional requirements best captures Congress's intent, for four reasons.

First, that interpretation of the "even though" clause best comports with Congress's language in other parts of § 22(b) and the legislative history. Congress repeatedly used the phrase "unavoidable side effects" interchangeably with "side effects that were unavoidable" in describing § 22(b)'s scope. For example, § 22(b)'s heading, which is a "tool[] available for the resolution of a doubt about the meaning of [the] statute," *Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998), is "[u]navoidable adverse side effects." Likewise, the Energy and Commerce Committee used the phrase "unavoidable side effects" in articulating § 22(b). *See* 1986 Report at 25-26 ("a vaccine manufacturer should not be liable for injuries or deaths resulting from *unavoidable side effects* even through [sic] the vaccine was properly prepared and accompanied by proper directions and warnings") (emphasis added). The phrase "unavoidable side effects" conveys a clear intent to hold manufacturers responsible for preventable vaccine injuries.

Moreover, given that Congress used "unavoidable side effects" synonymously with "side effects that were unavoidable" in both § 22(b)'s heading and the 1986 Report, it clearly did not think that the precise word order would be dispositive in properly construing the statute. The only plausible way to interpret § 22(b) consistent with Congress's interchangeable use of those two formulations ("side effects that were unavoidable" and "unavoidable side effects") is to read the "even though" clause not to modify the well-established meaning of "unavoidable," but rather to establish proper manufacturing

and proper directions and warnings as *additional* requirements.

Second, that interpretation best effectuates Congress's express purpose to codify comment k. The critical threshold issue under comment k is whether a product is "unavoidably unsafe." Only such products are eligible for exemption from strict liability, and, even then, manufacturers of such products must show that they were "properly prepared and accompanied by proper directions and warnings." Congress could not plausibly have intended to eliminate comment k's central threshold requirement—that a product's safety risks be shown to be "unavoidable"—through such indirect language. *See Ferrari*, 668 S.E.2d at 242 ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.") (internal quotations omitted). The better reading preserves that core requirement and harmonizes § 22(b)(1) with well-established standards under comment k.

Third, reading § 22(b) as requiring manufacturers to show that the harm from their vaccines was "unavoidable" gives meaning to the phrase "if the injury or death resulted from side effects that were unavoidable" in § 22(b)(1). As the Georgia Supreme Court noted in *Ferrari*, if Congress had meant to eliminate design-defect claims and preserve only claims alleging manufacturing defect and defective directions and warnings, the straightforward way to have done so would have been to provide that no vaccine manufacturer would be held civilly liable "if . . . the vaccine was properly prepared and was accompanied by proper directions and warnings." Instead, invoking the well-settled term "unavoidable,"

Congress provided that the exemption would apply only "if *the injury or death resulted from side effects that were unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (emphasis added). A construction of § 22(b)(1) that eliminates all design-defect claims reads the italicized language out of the statute and thus violates this Court's "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *TRW Inc. v. Andrews*, 534 U.S. 19, 31, 33 (2002) (internal quotations omitted); *accord Duncan v. Walker*, 533 U.S. 167, 174 (2001) (Court is "especially unwilling" to treat a statutory term as surplusage "when the term occupies so pivotal a place in the statutory scheme").

Fourth, reading § 22(b) to require a manufacturer to show "unavoidable" harm best comports with this Court's longstanding presumption against preemption of state-law claims. As this Court stated in *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008):

> When addressing questions of express or implied pre-emption, we begin our analysis with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States. Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors pre-emption.

Id. at 543 (internal quotations and citations omitted; alteration in original).

The presumption against preemption should be especially strong here, given that Congress imposed a "[g]eneral rule" expressly *preserving* state law, 42 U.S.C. § 300aa-22(a), and the "preemption" provision expressly displaces attempts under state law to *preclude* actions against vaccine manufacturers, *id.* § 300aa-22(e). *See Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009) ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.") (internal quotations omitted; alteration in original).

In sum, the best reading of § 22(b)—the one most consistent with the provision's plain language, the standards set forth in comment k, and this Court's canons of construction—is that a vaccine manufacturer is exempt from civil liability only upon a case-specific showing that the vaccine's side effects were unavoidable, and, even then, only if the vaccine was properly prepared and accompanied by proper directions and warnings.

C. The Third Circuit Misconstrued The Text And Structure Of The NCVIA

The Third Circuit misconstrued § 22's text and its relationship to the NCVIA as a whole. Specifically, the court found a "clear and manifest" congressional intent to preclude design-defect claims based on its reading of § 22(e), App. A30, which prohibits states from foreclosing civil actions that are otherwise "not barred by this part." 42 U.S.C. § 300aa-22(e). The court read "not barred by this part" as implying that

"other parts *of § 300aa-22* are designed to not only limit liability but bar some claims entirely." App. A27-A28 (emphasis added). The court accordingly thought that Congress must have "intended that subsections (b) and (c) should be an outright bar to some claims." App. A28. Relying on that premise, the court rejected petitioners' contention that manufacturers are exempt from liability only upon a showing that the particular vaccine's side effects were unavoidable as "contrary to the structure of the Act because it does not bar any design defect claims" but rather "subject[s] [such claims] to evaluation by a court." App. A29.

That interpretation misunderstands the NCVIA's text and structure. Section 22(e) refers to actions "not barred by this *part*," not actions not barred by this *section*. *See* Lawrence E. Filson, *The Legislative Drafter's Desk Reference* 222-26, 408-10 (1992) (distinguishing "section" and "part"). The provisions of the Act that bar civil actions are § 11(a)(2)(A) and § 21(a), which preclude claimants from "bring[ing]" a civil action if they have not sought compensation from the Vaccine Court first or if they have accepted that court's award. 42 U.S.C. §§ 300aa-11(a)(2)(A), 300aa-21(a); *see also id.* § 300aa-11(a)(2)(B) (referring to a "civil action which is barred under subparagraph (A)"); *id.* § 300aa-23(a) (creating procedures for actions "not barred by section 300aa-11(a)(2) of this title"). Section 22, by contrast, does not forbid "bring[ing]" any claims. Rather, it establishes "standards of responsibility" that preserve state liability rules while creating a narrow exemption if the vaccine's side effects are "unavoidable" (and the vaccine is properly prepared and accompanied by proper directions and warnings). *See supra* pp. 12-13, 28-41.

A standard for determining liability in a civil action is not the same as "barring" a civil action outright.

The 1986 Energy and Commerce Report confirms that Congress was referring in § 22(e) to the exhaustion requirements in § 11(a)(2) and § 21(a). That report stresses that the purpose of § 22(e) was to prevent states from going further than Congress in barring civil actions for vaccine-related injuries or deaths—for example, by creating their own mandatory compensation regimes. *See* 1986 Report at 27 ("State statutes that effectively foreclose individuals from bringing civil actions from vaccine-related injuries or deaths [are] pre-empted by this subsection. The Committee intends for this preemption to apply even where a State has established a compensation system as an alternative to filing civil actions.").

The fact that § 22(b) does not bar any claims, but instead establishes a limited exemption from liability, undermines the sole basis the Third Circuit gave for precluding design-defect claims—namely, that § 22(b) cannot be construed to require a "case-by-case analysis of whether particular vaccine side effects are avoidable." App. A29. Contrary to the Third Circuit's erroneous view, there is nothing unusual or unworkable about an exemption from liability being determined on a case-specific basis on the facts in the record. Such a case-specific determination is not only mandated by the plain language of § 22(b)(1) and consistent with decades of comment k jurisprudence, but also fully consistent with § 22(e) and the structure of the NCVIA as a whole.

II. THE NCVIA'S LEGISLATIVE HISTORY CONFIRMS THAT CONGRESS EXEMPTED MANUFACTURERS FROM LIABILITY ONLY IF THE VACCINE IS UNAVOIDABLY UNSAFE

Analysis of legislative history is a traditional tool of statutory construction. *See Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 610 n.4 (1991). That history here confirms that Congress did not categorically exempt vaccine manufacturers from all design-related liability. The legislative record demonstrates that Congress, the President, and vaccine manufacturers all understood—both in 1986, when the Act was first passed, and in 1987, when Congress amended the Act and enacted the funding mechanism necessary to give the law effect—that manufacturers would remain responsible for making their vaccines as safe as possible for patients.

A. The 1986 Act's Legislative History Confirms That Congress Intended To Preserve Certain Design-Defect Claims

The legislative record from the 99th Congress in 1986 confirms that Congress exempted vaccine manufacturers from liability only for harm that could not have been prevented by a better design.

In the Energy and Commerce subcommittee hearings on H.R. 5184, which eventually became the NCVIA, industry representatives recognized that § 22(b) would exempt manufacturers from civil liability only upon a case-specific showing that the side effects were truly unavoidable. Indeed, Lederle's president acknowledged that the bill would neither preclude plaintiffs from bringing claims based on failure to adopt a safer alternative vaccine nor make FDA approval a defense to such claims. *See Vaccine*

Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce, 99th Cong. 238-39 (1986) (statement of Robert Johnson) (noting that the bill would leave "open to litigation" claims "that the vaccines we sell are not as good as some alternative product, even though our vaccines have been approved by the Government as safe and effective"); *id.* at 239 (advocating enactment of a "strong government-standards defense" to design-defect claims); *see also id.* at 227-28 (statement of John Lyons, Executive Vice President, Merck) ("Merck has never sought to be relieved of its responsibility for making vaccines as pure, potent and safe as existing technology permits. *When we have fulfilled that responsibility*, however, unavoidably injured persons should be compensated through the no-fault system; they should not receive awards under our traditionally fault-based tort system."); *id.* at 229 ("[W]e would favor a proposal providing that such compliance [with federal vaccine regulations] would be a defense to any liability, just as it would be under the bill for punitive damage."); *id.* at 132 (statement of Martin H. Smith, President, American Academy of Pediatrics) (stating that § 22(b) exempts manufacturers from liability for "genuinely unavoidable injuries").

Congress did not adopt vaccine manufacturers' proposal to enact a federal regulatory compliance defense to claims asserting defective design. Moreover, the Energy and Commerce Committee specifically rejected a proposed amendment that would have provided that "a manufacturer's failure to develop [a] safer vaccine was not grounds for liability." 1987 Report at 691. As this Court has observed consistently, "[f]ew principles of statutory construction are

more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) (internal quotations omitted); *see also Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001). Congress's refusal to enact those measures confirms that it did not exempt vaccine manufacturers from design-defect liability for injuries that could have been prevented by a safer alternative design.

The 1986 Energy and Commerce Report accompanying the NCVIA further confirms Congress's intent. The report twice emphasized that § 22(b)(1) codified comment k, which only applies if a given product is "unavoidably unsafe." *See* 1986 Report at 26 (The Committee "intends that the principle in Comment K regarding 'unavoidably unsafe' products . . . apply to the vaccines covered in the bill . . . . [T]he Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort."). Moreover, in discussing § 23(c) of the Act, the 1986 Report confirmed that design-defect claims were not eliminated: "In establishing liability, for example, a plaintiff may demonstrate that the manufacturer produced a *defective vaccine* through clearly criminal behavior if that is what the evidence shows." *Id.* at 28 (emphasis added).

The Third Circuit read the 1986 Report to "support[] the conclusion that the [NCVIA] preempts all design defect claims." App. A35. The language it cited, however, does not support that conclusion. Only after stating that it was adopting comment k—thereby incorporating the requirement that a vaccine be found to be unavoidably unsafe—did the report go on to state that "if [claimants] cannot demonstrate

under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should [sic] pursue recompense in the compensation system, not the tort system." 1986 Report at 26. That sentence does not express intent to *eliminate* the threshold requirement that a vaccine's side effects be found to be unavoidable; it merely presumes that requirement to have been satisfied. This interpretation is confirmed by the statement in the same paragraph that Congress's adoption of comment k provides vaccine-injured persons with "an appealing alternative to the tort system," not a replacement for it. *Id.*

Finally, the floor comments immediately prior to House passage of the 1986 law further confirm Congress's intent. Representative Henry Waxman, the NCVIA's main sponsor, stated that, although "the bill would limit [a] child's ability to sue the manufacturer of the vaccine," "[i]f an injury is the result of bad vaccine *or one inadequately researched* or warned of, then the courts could still make awards." 132 Cong. Rec. at 30,760 (emphasis added). That statement tracks the three established requirements of comment k: courts can award compensation if the vaccine is not unavoidably unsafe ("inadequately researched"), improperly prepared ("bad vaccine"), or not accompanied by proper directions and warnings ("inadequately . . . warned of"). *See Toner*, 779 F.2d at 1432 ("The concept of an unavoidably unsafe product seems necessarily to depend on whether research was properly pursued."). Likewise, Representative Mario Biaggi supported the legislation by commenting that it "provides that manufacturers will not be liable for injuries or deaths resulting from unavoidable side effects *if* the vaccine was properly

prepared and accompanied by the proper directions and warnings." 132 Cong. Rec. at 30,762 (emphasis added). Those statements are at odds with any assertion that § 22 categorically exempted manufacturers from all design-related claims.

B. The Legislative History Of The 1987 Funding And Implementing Legislation Further Evidences Congressional Intent To Preserve Design-Defect Claims For Avoidable Side Effects

The legislative record of the 100th Congress also shows that § 22(b) did not exempt vaccine manufacturers from civil liability unless the injuries were caused by side effects that could not have been prevented. In an unusual feature to the legislation, the NCVIA did not take effect until Congress enacted separate legislation to fund it. *See* NCVIA § 323(a), 100 Stat. 3784. In 1987, Congress took up the key questions of whether and how to fund the legislation. In so doing, Congress also considered amendments to the NCVIA. As with those in the 99th Congress, the statements of all involved parties—Congress, the Reagan Administration, and vaccine manufacturers—reflected a shared understanding that § 22(b)(1) does not exempt vaccine manufacturers from design-defect claims for avoidable side effects.

Congressman Waxman reiterated his prior understanding that, "[i]f an injury is the result of bad vaccine or one *inadequately researched* or warned of, then the courts could still make awards." 1987 Hearing at 10, 13 (emphasis added).

The Reagan Administration, too, recognized that § 22(b) did not eliminate all manufacturer liability for design-related vaccine injuries. Speaking on behalf of the President, a Treasury Department official

observed that design-defect claims were not eliminated by § 22(b)(1):

> The [NCVIA] also would modify state tort laws . . . to preclude tort liability for "unavoidable" side effects in the absence of a finding that the vaccine was not properly prepared or was not accompanied by proper warnings.

Id. at 25 n.7 (statement of Dennis Ross). The Administration thus shared Congressman Waxman's view that § 22(b) exempted manufacturers from liability only for "unavoidable side effects," and, even then, only "in the absence of a finding" of manufacturing or labeling defect.

The Administration official then confirmed unequivocally that at least some design-defect claims were preserved by the NCVIA:

> A showing by the manufacturer that it had complied with all material Federal regulatory requirements would give rise to a rebuttable presumption that the vaccine was accompanied by proper warnings (*but would not give rise to a presumption that the vaccine was not defective in design*).

Id. (emphasis added).

Likewise, industry representatives redoubled their efforts to amend the NCVIA because they recognized, as they had in 1986, that § 22 permitted injured persons to bring design-defect claims against manufacturers. Lederle's Robert Johnson acknowledged that "the law provides no new defense at all" to claims that a vaccine's design was defective because of the practicability of a safer alternative. *Id.* at 84. Johnson advocated that "the liability provisions of the 1986 Act should be *amended*" to ensure that

manufacturers will "not face liability under a 'design defect' theory." *Id.* at 85 (emphasis added); *see also id.* at 102 (statement of David J. Williams, Connaught Laboratories) ("Of particular concern are so-called 'design defect' cases. . . . [T]he government standards defense should, at a minimum, be extended to design defect cases.").

Finally, in the section of the Budget Committee Report devoted to the 1987 legislation, the Energy and Commerce Committee specifically rejected the assertion that § 22(b) eliminates design-defect claims through a legislative determination that all vaccines are, as a categorical matter, "unavoidably unsafe":

> [T]he codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide *as a matter of law* the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. *The question is left to the courts* to determine in accordance with applicable law.

1987 Report at 691 (emphases added).[20]

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[20] The Third Circuit expressed uncertainty (App. A38-A39) whether "the Committee" referred to the Budget Committee or the Energy and Commerce Committee. Apparently for the same reason, the court doubted the Budget Committee Report's statement that the Energy and Commerce Committee had considered and rejected an amendment in 1986 to eliminate liability on the grounds of "a manufacturer's failure to develop [a] safer vaccine." 1987 Report at 691. Although the Budget Committee compiled and issued the report, the Energy and Commerce Committee wrote and approved the relevant language. Title IV of the report, entitled "Committee on Energy and Commerce," comprises "two Committee Prints approved by

Those 1987 statements provide compelling evidence of Congress's intent in enacting the NCVIA, because the 100th Congress had full power to reconsider the Act's liability provisions and indeed to nullify the NCVIA altogether by not passing the necessary funding legislation. In fact, Congress modified several substantive provisions of the Act, but did not adopt manufacturers' requests to modify the liability exemptions contained in § 22. The views of the 100th Congress, the statements made by the Administration, and the failed requests of vaccine manufacturers during the consideration of the 1987 legislation thus provide persuasive additional evidence that § 22(b) was not intended to provide an exemption from liability for injuries that could have been prevented by a safer design.[21]

III. INCENTIVIZING MANUFACTURERS TO DESIGN VACCINES TO PREVENT AVOIDABLE SIDE EFFECTS SERVES CONGRESS'S PURPOSES

Interpreting § 22(b)(1) to preclude design-defect liability only when the side effect in question was unavoidable serves two of Congress's main purposes in enacting the NCVIA—promoting vaccine safety and ensuring fair compensation to injured victims. *See* 42 U.S.C. § 300aa-1 (Congress sought "to achieve optimal prevention against adverse reactions to vaccines"); 1987 Report at 691 (the "system of Federal

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the Committee on Energy and Commerce for inclusion in the forthcoming reconciliation bill." *Id.* at 380.

[21] By contrast, *United States v. Price*, 361 U.S. 304 (1960), on which the Third Circuit relied (App. A39), stated that the views of a different Congress *15 years later* "form[ed] a hazardous basis for inferring the intent of" the Congress that enacted the provision at issue. *Id.* at 313.

no-fault compensation and other *rights of action* are intended to provide a stable vaccine market with care for the injured and *incentives for safety*") (emphases added). By contrast, providing manufacturers with blanket immunity from such claims would undermine patient safety without advancing any sound public policy.

A. Design-Defect Liability For Preventable Injuries Promotes Vaccine Safety And Fair Compensation To Victims

Preserving manufacturer liability for injuries resulting from preventable side effects advances Congress's purposes in enacting the NCVIA in three ways.

First, design-defect liability for preventable side effects encourages manufacturers to exercise due care in designing vaccines. The duty to compensate children and their families for avoidable injuries supplies a socially beneficial "incentive for safe design by the manufacturer." *Toner v. Lederle Labs.*, 828 F.2d 510, 513 (9th Cir. 1987) (Kennedy, J.); *see also Toner*, 732 P.2d at 310 ("[T]o immunize sellers of products ... from negligence claims would remove needed incentive[s] for safe design."); *Schafer*, 20 F.3d at 3 ("[T]he Act modifies, but does not eliminate, the traditional tort system, which ... provide[s] important incentives for the safe manufacture and distribution of vaccines.").

Further, the prospect of compensation for preventable injuries encourages manufacturers to keep up with scientific and technological advances, rather than continuing to market outmoded vaccines like Tri-Immunol for decades, despite the availability of a safer alternative. By contrast, conferring immunity from suit for continuing to sell outmoded vaccines

allows companies like respondent consciously to sacrifice patient safety in favor of increased profit. *See supra* p. 18; JA242, 245. This Court recognized the salutary effects of civil liability in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005): "'the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product[s] *so as to forestall such actions through product improvement.*'" *Id.* at 451 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)) (emphasis added); *see also id.* at 450 (noting "the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items").

A majority of state courts, too, have recognized that requiring case-specific showings that harmful side effects could not have been prevented promotes the public interest by incentivizing improved product design:

> [W]e believe that the policy reasons supporting a blanket approach are countervailed by those supporting a more selective application of the comment. . . .
>
> We believe that a more selective application will encourage, rather than discourage, improvements in prescription products. . . . [A] product which is as safe as current testing and research permits should be protected. The reverse is also true; a product which is not as safe as current technology can make it should not be protected.

Adams v. G.D. Searle & Co., 576 So. 2d 728, 732 (Fla. Dist. Ct. App. 1991); *see also, e.g.*, *Ferrari*, 668 S.E.2d at 242; *Toner*, 732 P.2d at 307.

In contrast, holding that the NCVIA precludes *all* design-related liability would not only vitiate the incentives for optimal vaccine design, but also undermine the public welfare by permitting manufacturer misconduct to go undeterred. *See* App. A35. Under the decision below, an injured child such as Hannah Bruesewitz cannot seek redress even if she can show, as respondent's own correspondence indicates, that the manufacturer *knew* its vaccine would cause harm that could be avoided by another design already on the market. *See supra* pp. 23-24. No sound policy reason supports insulating manufacturers from liability for such egregious misconduct, and nothing in the NCVIA or its legislative history supports such a draconian result.[22]

Second, allowing design-defect claims for avoidable side effects complements FDA regulation of vaccine safety. FDA does not condition approval of a vaccine on the design being the safest among reasonably available alternatives. Nor does it ensure that licensed vaccines keep pace with technological and scientific advances. *See supra* pp. 6-9. Thus, although state and federal law have parallel objectives—both seek to promote vaccine safety—only the civil justice system provides manufacturers with the incentive to continue to improve the safety of their products beyond FDA's minimum requirements. *See Bates*, 544 U.S. at 451. Indeed, this Court recognized in *Wyeth v. Levine* that the federal regime regulating

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[22] By ensuring optimal vaccine design, design-defect claims for avoidable injuries also promote public confidence in vaccine safety, which, in turn, promotes childhood immunization. *See, e.g.*, Wash. Rev. Code Ann. § 70.95M.115 note (Supp. 2010) (limiting mercury content in certain vaccines "to maintain public confidence in vaccine programs, so that the public will continue to seek vaccinations").

drugs, which is comparable in relevant respects to the federal regime regulating vaccines, does not create the same incentives as state law for manufacturers to act reasonably. *See* 129 S. Ct. at 1197-98.

Civil actions also help promote FDA's regulation of vaccines by uncovering information about adverse side effects not generally available to federal regulators. In *Levine*, this Court recognized shortcomings in FDA's ability to collect information on products: "manufacturers have superior access to information about their" products, as compared to FDA, a condition that is "especially" true in "the postmarketing phase as new risks emerge." *Id.* at 1202; *see also supra* p. 9 (describing FDA's limited postmarketing surveillance). By "uncover[ing] unknown drug hazards" and "motivat[ing] injured persons to come forward with information," *Levine*, 129 S. Ct. at 1202, civil actions help to bridge FDA's informational gap.

Moreover, as this Court also recognized in *Levine*, throughout FDA's history, well-respected independent observers have found that the agency lacks the resources and tools to serve as the sole protector of public health. *See id.* at 1202 n.11. A recent consensus report from the Institute of Medicine found that "[f]unding for vaccine safety monitoring and research has not grown commensurate with the widening task (e.g., a growing list of recommended vaccines) and parallel investment in vaccine supply."[23] And a House Committee on Government Reform study found "significant conflicts of interest" within FDA's Vaccines and Related Biological Products

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[23] Institute of Medicine, *Priorities for the National Vaccine Plan* 2:17-18 (Dec. 2009).

Advisory Committee and CDC's Advisory Committee on Immunizations Practices. Majority Staff of H. Comm. on Gov't Reform, 106th Cong., Conflicts of Interest in Vaccine Policy Making 16 (Aug. 21, 2000) ("Gov't Reform Report"), *available at* http://www.generationrescue.org/pdf/3.5.pdf; *see id.* at 1 ("[C]onflict of interest rules employed by the FDA and the CDC have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have been given waivers to participate in committee proceedings.").[24] Such reports demonstrate the important role that private civil lawsuits play in complementing FDA regulation and promoting vaccine safety.

Third, ensuring that the courthouse doors remain open to claimants seeking recovery for injuries resulting from avoidable vaccine side effects promotes Congress's goal of compensating these innocent victims. Although the Compensation Program was "designed to work faster and with greater ease than the civil tort system" in handling the mine-run case, *Whitecotton*, 514 U.S. at 269, it was not designed to supplant tort law's compensatory function. *See, e.g.*, 1986 Report at 3 (liability provisions "deal[] with the *additional remedies* that are available to vaccine-injured persons should they elect to reject a judgment and award made under the compensation program and to take action directly against a vaccine manufacturer") (emphasis added).

Court actions are essential because they provide injured victims with tools not available in the Vaccine

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[24] The Report focused on Wyeth's RotaShield vaccine, which was pulled from the market due to serious adverse reactions just 13 months after FDA approval. *See* Gov't Reform Report at 8-9.

Court. Significantly, because special masters "adjudicate [claims] informally, within strict time limits, subject to similarly expeditious review," *Whitecotton*, 514 U.S. at 270 (citations omitted), Vaccine Court claimants "do not have a right to conduct discovery."[25] *See* 42 U.S.C. § 300aa-12(d)(2)(E), (d)(3). Discovery is purely at the discretion of special masters, who normally do not permit it. *See id.* § 300aa-12(d)(3) ("There may be no discovery in a proceeding on a petition other than the discovery required by the special master."); *Deloatch* Order at 3 (collecting cases).

Given the limitations of the Compensation Program, the right to seek judicial relief is critical. *See* 1986 Report at 16 (referring to the "wider inquiry ... appropriate in a civil action"). Without discovery, causation—which is extremely difficult in vaccine cases—would be nearly impossible to prove. Moreover, only through civil discovery—which uncovered, for example, the internal correspondence showing that respondent knew that the whole-cell pertussis component of Tri-Immunol was more toxic than Tri-Solgen's split-cell version, but nevertheless abandoned efforts to improve its vaccine for economic reasons, *see* JA242, 245—will claimants be able to gather evidence necessary to bring such public health threats to light. Congress preserved victims' right to seek relief through the civil justice system precisely because the Vaccine Court process contains limits.

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[25] Published Ruling Quashing Subpoena at 3, *Deloatch v. Secretary of HHS*, No. 1:09-vv-00171-UNJ (Fed. Cl. Apr. 27, 2010) ("*Deloatch* Order").

B. Design-Defect Liability Would Not Destabilize The Vaccine Market

Echoing arguments made by respondent, the Third Circuit expressed concern that vaccine manufacturers would exit the market and destabilize the vaccine supply without full immunity from all design-defect claims. *See* App. A35-A36; *see also* Br. in Opp. 16-19, 23 (arguing that a "new litigation threat" will cause manufacturers to leave the market). As an initial matter, the Third Circuit cited no empirical data to support that concern, "and[] the claim does not prove itself." *Schafer*, 20 F.3d at 6.

In all events, that policy argument merely reiterates the objections that Congress heard and rejected more than 20 years ago. Those objections ring especially hollow given the unprecedented steps Congress took to "reduc[e] the litigation and insurance costs" for manufacturers. *Id.* at 4. Through the Compensation Program, the federal government relieves manufacturers of the primary burden of compensating victims of vaccine-related injuries. Congress also "discourage[d] victims from bringing . . . traditional tort cases by providing fairly generous, more easily obtainable, Vaccine Court awards." *Id.* at 4-5. "A victim who obtains such an award may hesitate to give up that bird in the hand in return for a larger, but more speculative, tort law award. And, a petitioner to whom the Vaccine Court gives nothing may see no point in trying to overcome tort law's yet more serious obstacles to recovery." *Id.* at 5.

For claimants who elect to reject the Vaccine Court's judgment and file a civil action, Congress enacted numerous additional measures to reduce manufacturers' liability exposure: immunity from damages for "unavoidable" side effects and a limited

regulatory compliance presumption of adequate warnings to support it (§ 22(b)(1), (2)); application of the learned intermediary doctrine and elimination of claims based on failure to provide direct warnings to patients (§ 22(c)); a tripartite trial procedure (§ 23(b), (c), (d)(1)); and a heightened standard for punitive damages (§ 23(d)(2)). But, despite manufacturers' fervent requests, Congress declined to go farther by eliminating *all* design-defect liability for vaccine injuries. And Congress certainly made no effort to relieve manufacturers like Wyeth of liability for preventable harms caused by outmoded vaccines subsequently withdrawn from the market. Those considered legislative policy choices warrant this Court's respect.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

JOHN EDDIE WILLIAMS
JOHN T. BOUNDAS
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway
Suite 600
Houston, Texas 77017-5051
(713) 230-2200

COLLYN A. PEDDIE
THE LAW OFFICES OF
COLLYN PEDDIE
440 Louisiana, Suite 1710
Houston, Texas 77002-1689
(713) 422-1205

DAVID C. FREDERICK
Counsel of Record
DEREK T. HO
BRENDAN J. CRIMMINS
JANIE N. KUCERA
KELLOGG, HUBER, HANSEN,
TODD, EVANS & FIGEL,
P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

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RESPONDENT'S BRIEF

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IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD, AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES AND LEDERLE LABORATORIES,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR RESPONDENT

DANIEL J. THOMASCH
RICHARD W. MARK
E. JOSHUA ROSENKRANZ
LAUREN J. ELLIOT
JOHN L. EWALD
ORRICK, HERRINGTON & SUTCLIFFE LLP
51 W. 52nd Street
New York, NY 10019
(212) 506-5000

KATHLEEN M. SULLIVAN
Counsel of Record
FAITH E. GAY
SANFORD I. WEISBURST
WILLIAM B. ADAMS
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Ave., 22nd Flr.
New York, NY 10010
(212) 849-7000
kathleensullivan@quinnemanuel.com

Counsel for Respondent

July 23, 2010

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 provides: "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1).

The question presented is:

Does Section 22(b)(1) preempt vaccine design-defect claims categorically, or must a vaccine manufacturer also show, case by case, that the side effects at issue could not have been avoided by some differently designed vaccine?

RULE 29.6 STATEMENT

Respondent Wyeth, Inc. is now known as Wyeth LLC. Wyeth LLC states that it has a parent corporation, Pfizer Inc., and that Pfizer Inc. owns 10% or more of Respondent's membership interests.

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IN THE

Supreme Court of the United States

No. 09-152

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD, AND IN THEIR OWN RIGHT,

Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES AND LEDERLE LABORATORIES,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR RESPONDENT

INTRODUCTION

"Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. REP. NO. 99-908, pt. 1, at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345 ("1986 House Report"). For example, between 1934 and 1984, diphtheria, tetanus and pertussis ("DTP") vaccines helped reduce re-

ported cases of pertussis (commonly known as "whooping cough") by 99%. See STAFF OF SUBCOMM. ON HEALTH AND THE ENVIRONMENT, 99th Cong., CHILDHOOD IMMUNIZATIONS 10 (Comm. Print 1986) ("Subcomm. Report"). Inadequate vaccination can lead to sudden outbreaks of infectious but preventable disease, as a recent epidemic of whooping cough that has killed at least five infants in California tragically illustrates.[1]

Petitioners' account of the origins of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.* (the "Vaccine Act"), hardly mentions the spectacular success of childhood vaccination in protecting public health. Nor do Petitioners explain that Congress had *two* goals in enacting the Vaccine Act. One goal, to be sure, was to provide a streamlined and generous administrative compensation scheme for those few children who suffer rare side effects from vaccines. The other goal, which Petitioners barely acknowledge, was to ensure the continued supply of essential childhood vaccines by reducing the burden of civil litigation that had driven a number of vaccine manufacturers from the market, threatening the nation's vaccine supply. See Brief For The United States As *Amicus Curiae*, *Am. Home Prods. Corp.* v. *Ferrari*, No. 08-1120 (Jan. 29, 2010) ("U.S. *Ferrari* Br."), at 2.

An important means of serving the latter goal is the preemption provision of the Vaccine Act, Section 22(b)(1). This provision bars state-law tort liability

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[1] *See* Molly Hennessy-Fiske, *Whooping Cough Fight Broadens*, L.A. TIMES, July 20, 2010, at AA; Jesse McKinley, *Whooping Cough Kills 5 in California; State Declares an Epidemic*, N.Y. TIMES, June 24, 2010, at A15.

against manufacturers of childhood vaccines for all possible claims but two, manufacturing defect and failure to warn:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. 300aa-22(b)(1). By enacting Section 22(b)(1), Congress sought to prevent future threats to the nation's vaccine supply by precluding any recurrent wave of state-law litigation against vaccine manufacturers like the one that had helped prompt enactment of the Vaccine Act.

Other provisions of the Vaccine Act ensure that the safety and efficacy of vaccine design is governed by a comprehensive national regulatory scheme rather than a patchwork of state tort laws. The Act provides for active federal encouragement and funding of vaccine research, 42 U.S.C. 300aa-19, 300aa-27, and for active federal oversight of vaccine development and safety beyond that provided by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq*. Before approval, vaccines undergo comprehensive clinical trials, and after approval, they are actively monitored for adverse events. Once a vaccine is licensed, its design may not be altered without the prior approval of the Food and Drug Administration ("FDA"). 21 C.F.R. 601.12(b)(2)(i).

Having barred all state-law claims other than manufacturing-defect and failure-to-warn claims, the

Vaccine Act provides for a generous administrative compensation scheme for vaccine-related injuries or deaths, funded by an excise tax on vaccines. Claimants under this scheme need not prove fault; they need show only that they received a vaccine listed in the federal "Vaccine Injury Table" and sustained an injury specified in the Table within the time periods specified in the Table, or prove that a listed vaccine caused an injury. 42 U.S.C. 300aa-11(c)(1)(C). Successful claimants may recover *uncapped* medical expenses, medical care and projected lost earnings, and up to $250,000 for pain and suffering, *id.* 300aa-15(a), and claimants may recover attorney's fees and costs whether or not they receive compensation, *id.* 300aa-15(e). The compensation scheme has awarded to date over ***$1.8 billion***.

Petitioners would rewrite the text and ignore the structure of the Vaccine Act to render Section 22(b)(1) a nullity. In Petitioners' view, vaccine manufacturers must litigate case by case whether they could have sold some alternative vaccine, allegedly safer than the vaccine that was administered to the plaintiff. Preemption, in Petitioners' view, is available only after a manufacturer has gone through a full trial and proved that no differently designed vaccine would have avoided the injury. Thus, in Petitioners' view, the express preclusion of liability in Section 22(b)(1) changed nothing: vaccine injury claimants remain as free after the Act's passage as before to bring all manner of state-law tort claims challenging vaccine safety, with the federal no-fault compensation scheme merely a checkpoint en route to civil litigation under state law.

The Third Circuit properly rejected this misreading of Section 22(b)(1), finding that this provision

categorically preempts state design-defect claims. Accord, U.S. *Ferrari* Br. 9. That interpretation was correct, and the judgment below should be affirmed.

STATEMENT

A. The Nature And Role Of Vaccines

Vaccines have "changed humanity" by enabling the near eradication of numerous infectious diseases. National Vaccine Program Office, *Draft Strategic National Vaccine Plan*, at 25 (Nov. 26, 2008), available at www.hhs.gov/nvpo/vacc_plan/2008plan/draftvaccineplan.pdf (last visited July 21, 2010). The necessary predicate for this success is the almost universal vaccination of children, which promotes "herd immunity" and thus reduces the spread of contagious disease even to those who are unimmunized or incompletely immunized. Smallpox and polio have been entirely eradicated in the United States, while the incidence of other diseases has been radically reduced. Centers for Disease Control and Prevention, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MMWR 241 (Apr. 2, 1999).

Vaccines differ from most drugs in that they are biological products, not precise chemical compounds, and thus some variation is inherent in their production. As the Task Force on Safer Childhood Vaccines, established by the Secretary of Health and Human Services ("HHS") under the Act, has observed, "[s]afety is not a condition that can be absolutely guaranteed" with vaccines. National Institute of Allergy and Infectious Diseases, Task Force on Safer Childhood Vaccines, *Final Report and Recommendations*, at 2 (1998). Vaccines also differ from drugs in that they are administered broadly to a

healthy population. *Ibid.* For these reasons, vaccines are subject to closer federal monitoring than are drugs.

B. The Genesis Of The Vaccine Act

Protecting public health through the successful vaccination of the population depends upon maintaining a robust and stable supply of vaccines. In enacting the Vaccine Act, Congress recognized and sought to avert the threat to the vaccine supply posed by escalating litigation against vaccine manufacturers. See 1986 House Report at 4-5; see also Charles F. Hagan, *Vaccine Compensation Schemes*, 45 FOOD DRUG COSM. L.J. 477, 479 (1990) ("The increasing liability exposure of childhood vaccine manufacturers has been a significant factor in the decline in the number of these manufacturers.").

In the early 1980s, only a handful of manufacturers produced childhood vaccines. See Subcomm. Report at 85. By 1984, for example, only three commercial companies supplied DTP vaccine for the U.S. market: Lederle Laboratories,[2] Connaught Laboratories, Inc., and Wyeth Laboratories. *Id.* at 67-68. While only eight lawsuits were filed against DTP manufacturers from 1979 through 1981, see Geoffrey Evans, *Update on Vaccine Liability in the United States*, 42 CLINICAL INFECTIOUS DISEASES S130, S134 (2006) ("Evans"), the number of such lawsuits skyrocketed after the 1982 broadcast of "DPT: Vaccine Roulette," a report that alleged dangers from DTP vaccines, see Committee to Review the Adverse Consequences of Pertussis

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[2] Lederle manufactured the TRI-IMMUNOL® vaccine at issue here. In 1994, Wyeth Laboratories' parent company, American Home Products Corporation, acquired Lederle's parent company, American Cyanamid Company. J.A. 132.

and Rubella Vaccines, Division of Health Promotion and Disease Prevention, Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines* 19 (Christopher P. Howson *et al.* eds., 1991).

This escalating wave of litigation imposed crushing litigation costs on vaccine manufacturers and carried the potential for large judgments. See Subcomm. Report at 87; 1986 House Report at 6. In 1985 alone, 219 lawsuits were filed against the three DTP manufacturers. See Evans at S134. Overall, from 1980 to 1986, lawsuits filed against vaccine manufacturers sought more than $3.5 billion in damages. See Derry Ridgway, *No-Fault Vaccine Insurance: Lessons From The National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 60-61 (1999). In 1984, Lederle estimated that its potential liability from DTP vaccine lawsuits was 200 times its annual sales for the vaccine. Subcomm. Report at 69. Such potential liability made it difficult for vaccine manufacturers to obtain affordable product liability insurance. 1986 House Report at 6-7.

Many claims alleged that DTP vaccines, by virtue of their design, were unreasonably dangerous and thus defective products. Congress heard testimony that the plaintiffs in these cases "routinely ... contend that the vaccines [manufacturers] sell are not as good as some alternative product, even though our vaccines have been approved by the Government as safe and effective and even though their use is recommended by all responsible medical authorities." *Vaccine Injury Compensation: Hearing on H.R. 1780, H.R. 4777, and H.R. 5184 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 99th Cong. 238 (1986) ("1986

Hearing") (statement of Robert B. Johnson, President, Lederle Labs. Div., Am. Cyanamid Co.).

The DTP vaccine litigation crisis caused manufacturers to consider abandoning the vaccine market, putting the supply of essential childhood vaccines at risk in the United States. In late 1984, Connaught and Wyeth Laboratories withdrew from the market. Subcomm. Report at 68.[3] That same year, Lederle, the one remaining manufacturer, experienced production problems. *Id.* at 69.

In considering the Vaccine Act, Congress found that "[t]he number of childhood vaccine manufacturers [had] declined significantly," 1986 House Report at 4, while the few that remained had begun "to question their continued participation in the vaccine market," *id.* at 7. This "unstable and unpredictable childhood vaccine market," *id.* at 5, led to "a short term crisis of availability of DTP vaccine," Subcomm. Report at 68. The shortage became so dire that the Centers for Disease Control and Prevention ("CDC") recommended stretching out the vaccination schedule, even at the cost of diluting children's protection. *Id.* at 69. Congress recognized that the "withdrawal of even a single [additional] manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." 1986 House Report at 7.

In addition to considering the threat that civil litigation posed to the vaccine supply, the 99th Congress also considered the concerns of individuals

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[3] Connaught returned to the market in 1985 after obtaining liability insurance coverage for its vaccines. Subcomm. Report at 69-70.

claiming they (or their children) had been injured by vaccines. Congress heard testimony that the tort system was failing to compensate vaccine-related injuries adequately and that the cost of litigation was high and recoveries uncertain and often delayed. See 1986 House Report at 6.

C. The Vaccine Act

In 1986, Congress enacted the Vaccine Act to respond to both the need to protect the public health by preserving a stable vaccine supply and the desire to find a more effective means than the civil tort system to compensate victims of vaccine-related injuries. In order to avert state tort litigation that might drive vaccine manufacturers from the market, Congress precluded all state-law civil tort liability other than for claims of manufacturing defect and some limited failures to warn. To promote the development and manufacture of even safer and more efficacious vaccines, Congress established a National Vaccine Program providing for comprehensive government involvement in the development, approval, and monitoring of vaccines. And in order to provide swift and reliable compensation to the few who suffer adverse side effects from vaccination, Congress established a generous no-fault administrative compensation system. The Act's preemption and compensation provisions apply solely to the twelve categories of vaccines that are routinely administered to children.[4]

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[4] The twelve currently covered categories of childhood vaccines are listed on the Vaccine Injury Table. 42 C.F.R. 100.3(a). To be listed on the Table, a category of vaccine must be "recommended for routine administration to children" by the CDC, 42 U.S.C. 300aa-14(e)(2), and Congress must fund awards by subjecting that category to the excise tax, Omnibus Budget Recon-

1. The Preemption Provision

Section 22(a) of the Vaccine Act provides that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death," except "as provided in subsections (b), (c) and (e) of this section." 42 U.S.C. 300aa-22(a). Section 22(b)(1), immediately following, specifies such limits on state-law civil tort liability:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

Id. 300aa-22(b)(1). Section 22(b)(1) thus bars all civil tort liability against the manufacturers of childhood vaccines covered by the Act provided that the vaccine is "properly prepared" (*i.e.*, made according to its formula) and "accompanied by proper directions and warnings."

Section 22(b)(2) further provides that "a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 262 of this title (including regulations issued under such provisions)," unless a manufacturer engaged in fraud or withheld material information from FDA in obtaining and maintaining

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ciliation Act of 1993, Pub. L. No. 103-66, § 13632(a)(3), 107 Stat. 312, 646 (1993).

approval of the vaccine. 42 U.S.C. 300aa-22(b)(2); see also *id.* 300aa-23(d)(2)(A)-(B).

Section 22(e), an additional preemption provision, makes clear that the federal Act strikes the appropriate balance by limiting the States' ability to go further than the Act itself in eliminating civil liability against vaccine manufacturers. This section provides that "[n]o State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part." 42 U.S.C. 300aa-22(e).

2. The Development, Approval, And Monitoring Scheme

Childhood vaccines are subject to rigorous and comprehensive regulation under the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. 301 *et seq.*; 42 U.S.C. 262(a). The Vaccine Act supplements FDA's approval and supervision regime by directing multiple federal agencies to assist industry in promoting research into safer and more efficacious vaccines. See U.S. *Ferrari* Br. 14-15.

Federal Food, Drug, and Cosmetic Act and regulations. An applicant for a biologics license must provide extensive information to FDA's Center for Biologics Evaluation and Research ("CBER"), including data on laboratory and clinical studies,[5]

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[5] Because vaccines are administered to healthy individuals, clinical trials for vaccines typically require many more study participants than clinical trials for other drugs. Compare Norman W. Baylor & Karen Midthun, *Regulation and testing of vaccines*, in VACCINES 1611, 1617 (Stanley A. Plotkin, *et al.* eds., 5th ed. 2008) (the number of study participants in recent vac-

manufacturing methods, product samples, proposed labels, and addresses of all manufacturing facilities. 21 C.F.R. 601.2. An applicant for a biologics license also must allow CBER to perform an in-depth inspection of the facility and the vaccine manufacturing process to assure compliance with all applicable federal standards. *Id.* 601.20. If, after the clinical trial and related review, FDA determines that the product "meet[s] the applicable requirements," a license "shall be issued" and "shall be valid until suspended or revoked." *Id.* 601.4(a).

To be released, each lot of vaccine must pass safety, sterility, purity, and identity tests. See 21 C.F.R. 610.11, 610.12, 610.13, 610.14; see also J.A. 87-90 (describing the testing process at the time the lot of TRI-IMMUNOL® at issue in this case was released). If FDA determines that a batch, lot, or other quantity of released vaccine presents an imminent or substantial hazard to the public health, the Secretary of HHS must issue an immediate order recalling the product. 42 U.S.C. 262(d)(1). An approved vaccine that is later considered by FDA to have an unsafe design may be removed from the market. 21 C.F.R. 601.5(b)(1)(vi).

Once a vaccine has been approved for distribution, any change to the "qualitative or quantitative formulation" of a vaccine—including a design change—requires re-submission to and re-approval by FDA prior to distribution. 21 C.F.R. 601.12(b)(2)(i). Con-

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cine efficacy trials has ranged from thousands to tens of thousands) with 21 C.F.R. 312.21(c) (describing prescription drug clinical trials as usually including several hundred to several thousand subjects). See also U.S. *Ferrari* Br. 14 ("New childhood vaccines ... are put through some of the most exhaustive and largest clinical trials of any FDA-approved product.").

trary to Petitioners' suggestion (Br. 7-8), vaccine manufacturers are *not* free to change the design of a vaccine without prior approval by the government. Regulations allow certain minor changes without pre-approval, see 21 C.F.R. 601.12(c), (d), but design changes are not among them.

Following issuance of a license, the license-holder is obligated to review and to regularly report all adverse experiences reported by users of the product or any member of the public. 21 C.F.R. 600.80. Failure either to make regular reports or to keep records may result in revocation of the license. *Id.* 600.80(j). In addition to the reporting requirements for manufacturers, healthcare providers that administer a vaccine on the Vaccine Injury Table are required by law to report the occurrence of an injury listed on that Table. 42 U.S.C. 300aa-25(b)(1).

To facilitate this reporting scheme, CDC and FDA co-sponsor the Vaccine Adverse Event Reporting System ("VAERS"), a national vaccine safety surveillance program that acts as a central repository for reports of adverse events that occur following vaccination. See 21 C.F.R. 600.2(d), 600.80(c); see also http://vaers.hhs.gov (last visited July 21, 2010). VAERS is used "to detect possible signals of adverse events associated with vaccines."[6] Such "signals" are often used to generate a hypothesis that requires further study. Inter-Agency Vaccine Group, *A Comprehensive Review of Federal Vaccine Safety Programs and Public Health Activities* 18 (Dec. 2008) ("Comprehensive Review"), available at http://www.

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[6] FDA, *Vaccine Adverse Events*, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/default.htm (last modified Oct. 19, 2009).

hhs.gov/nvpo/nvac/subgroups/vaccinesafety.html#vaccine (last visited July 21, 2010). The Vaccine Safety Datalink ("VSD"), "a collaborative effort between the CDC's Immunization Safety Office and eight managed care organizations,"[7] is an active surveillance system of vaccine-related adverse events that is an "extremely powerful tool to test hypotheses regarding the association of vaccines and health outcomes." Comprehensive Review at 19. VSD "serves an important role in the nation's vaccine safety system by providing the infrastructure for carefully designed epidemiological studies." *Ibid.* There is no VSD counterpart for drugs.

The Vaccine Act. The Vaccine Act supplements FDA's extensive regulatory regime, aiming "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1; see also *id.* 300aa-2(9), 300aa-6 (providing funding for this effort). As Petitioners neglect to mention (Br. 7 & nn.3-4), the Act creates a National Vaccine Program ("NVP") that enlists a dozen federal agencies (including FDA) to promote the development of improved, safer vaccines for use in immunization programs nationwide. 42 U.S.C. 300aa-27(a)(1).

Additionally, the Vaccine Act adopts a "[m]andate for safer childhood vaccines" and assigns responsibility for that mandate to the Secretary of HHS. 42 U.S.C. 300aa-27. The Secretary is directed to "promote the development of childhood vaccines that

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[7] CDC, *Vaccine Safety Datalink (VSD) Project*, http://www.cdc.gov/vaccinesafety/Activities/vsd.html (last modified Feb. 17, 2010).

result in fewer and less serious adverse reactions" than those on the market at the time, and to "promote the refinement of such vaccines." *Id.* 300aa-27(a)(1). The Secretary is also charged with "mak[ing] or assur[ing] improvements in ... the licensing, manufacturing, processing, testing, labeling, warning, use instructions ... and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." *Id.* 300aa-27(a)(2); see also *id.* 300aa-27(b) (the Secretary shall "establish a task force on safer childhood vaccines" to make recommendations on vaccine safety and effectiveness). A civil action may be filed against the Secretary for failure to fulfill this role. *Id.* 300aa-31.

Non-governmental perspectives are brought into the process through the National Vaccine Advisory Committee ("NVAC"), 42 U.S.C. 300aa-5, and the Advisory Commission on Childhood Vaccines ("ACCV"), *id.* 300aa-19. These two bodies, which have medical and lay members, are charged with advising HHS and making recommendations to the NVP Director about the implementation of his responsibilities under the Vaccine Act. For example, NVAC is charged with "recommend[ing] research priorities and other measures the Director ... should take to enhance the safety and efficacy of vaccines." *Id.* 300aa-5(b)(2). The NVAC and ACCV also are part of the task force on safer childhood vaccines called for by Section 27(b) of the Act. *Id.* 300aa-27(b).

Since the Act became effective, more than 20 childhood vaccines, including new vaccines against pneumococcal disease, meningococcal disease, hepatitis A, and varicella (chickenpox), have obtained FDA approval and been brought to market. See generally FDA, *Vaccines Licensed for Immunization and*

Distribution in the US With Supporting Documents, http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm (last modified June 3, 2010); Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* 188-90 (2004).

3. The Compensation Scheme

The Vaccine Act offsets Section 22(b)(1)'s preclusion of all civil claims other than manufacturing defect and failure to warn by "establish[ing] a scheme of recovery designed to work faster and with greater ease than the civil tort system." *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995). This compensation program, implemented through the Office of Special Masters within the United States Court of Federal Claims known as "Vaccine Court," 42 U.S.C. 300aa-12(c), (d), provides generous no-fault compensation for vaccine-related injury claims.

A claim for vaccine-related injury is asserted by filing a petition in Vaccine Court. 42 U.S.C. 300aa-11(a). The Vaccine Act provides for the creation, and regular update, of the Vaccine Injury Table, which lists symptoms and injuries that medical research has found associated with a covered vaccine. *Id.* 300aa-14. The Table "turns the old maxim on its head by providing that if the *post hoc* event happens fast, *ergo propter hoc*." *Whitecotton*, 514 U.S. at 270. A petitioner who proves that he or she received a listed vaccine and suffered symptoms set forth on the Table has made a *prima facie* case for recovery and need not prove causation; the presumption of causation is rebutted only if HHS demonstrates by a preponderance of the evidence that the injury was

not vaccine-related. 42 U.S.C. 300aa-13(a)(1); *Whitecotton*, 514 U.S. at 270-71.

A petitioner claiming a Table injury need not prove that the vaccine was defective in any way. 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a). For a non-Table injury, a petitioner must show causation, but again, need not show any defect in the vaccine or misconduct by the manufacturer. *Id.* 300aa-11(c)(1)(C)(ii). Congress recognized that the no-fault compensation program would provide a remedy for some vaccine-related injuries that would not succeed under state tort law. See 1986 House Report at 13 ("because of many States' standards of proof of liability, many vaccine-injured persons are presently without legal remedy under current tort law").[8]

A Vaccine Court petitioner who establishes a vaccine-related injury is entitled to compensation for all medical expenses, remedial care, rehabilitation, counseling, long-term care, projected lost earnings, and up to $250,000 for pain and suffering. 42 U.S.C. 300aa-15(a). To ensure access to the compensation program, Vaccine Court awards attorney's fees and costs to the petitioner, whether or not any compensation is awarded. *Id.* 300aa-15(e). Payments of compensation, fees, and costs to petitioners are funded by an excise tax on vaccines. 26 U.S.C. 9510.

In just two decades, Vaccine Court has awarded more than $1.8 billion to nearly 2,500 petitioners, resulting in an average award exceeding $750,000. Health Resources and Services Administration, *National Vaccine Injury Compensation Program Sta-*

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[8] Congress acknowledged that use of the Table would result in awarding compensation "to some children whose illness is not, in fact, vaccine-related." 1986 House Report at 18.

tistics Report (July 14, 2010), http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (last visited July 21, 2010).

D. Pertussis And Pertussis Vaccines

The vaccine at issue in this case, TRI-IMMUNOL®, contributed to a dramatic decrease in illness and death from pertussis—a highly communicable respiratory disease that is especially dangerous to children under two years old and can leave survivors with severe neurologic disorders. Subcomm. Report at 8-10. In 1934, there were 265,269 reported cases of pertussis and 7,518 deaths in the United States. *Id.* at 10. TRI-IMMUNOL® was approved for marketing in the United States on April 27, 1943. J.A. 134, ¶ 11.[9] After forty years of widespread use of TRI-IMMUNOL® and other DTP vaccines, the incidence of pertussis dropped to 2,276 reported cases and only twelve deaths by 1984. Subcomm. Report at 10.

TRI-IMMUNOL® is composed of diphtheria and tetanus toxoids and a "whole-cell" pertussis vaccine component; its pertussis component employs a suspension of whole, killed pertussis cells to stimulate an immune response. J.A. 85, ¶ 7.[10] A handful of

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[9] Following the initial approval, Lederle submitted modified license applications resulting from changes to applicable regulations or updated manufacturing procedures in 1948, 1953, and 1970. J.A. 134-35, ¶¶ 12-16.

[10] The pathogens used in whole-cell DTP vaccines are neither "potent" nor "deadly" as Petitioners assert (Br. 3), but rather are killed during the manufacturing process. The resulting vaccine is safe to the recipient, while conferring immunity against disease. See generally American Academy of Pediatrics, *Questions and Answers about Vaccine Ingredients* (Oct. 2008), http://www.aap.org/immunization/families/faq/Vaccineingredients.pdf (last visited July 21, 2010).

reports in the 1940s and 1950s (see Pet. Br. 17 n.12) raised questions whether the vaccine had caused severe adverse reactions to a few recipients, but these concerns proved illusory.[11] In 1995, HHS removed "residual seizure disorder" (one of the alleged injuries in this case) as a "Table Injury" associated with the DTP vaccine because epidemiological evidence showed that there was no "*medical evidence to support*" a presumed causal relationship. *National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table*, 60 Fed. Reg. 7,678, 7,691 (Feb. 8, 1995) (emphasis added).

Contrary to Petitioners' suggestion (Br. 1, 17-19), Lederle could not have marketed, as of 1992 (the time of the vaccination at issue in this case), some supposedly safer alternative to whole-cell DTP vaccines for infants. Petitioners suggest that one alternative was supposedly Tri-Solgen, a "fractionated cell" vaccine once manufactured by Eli Lilly & Co. But Tri-Solgen was never shown to cause fewer neurological disorders or other severe side effects than whole-cell vaccines (it merely caused less fever and pain at the injection site). *Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Proposed Rule*, 50 Fed. Reg. 51,051-52 (Dec. 13, 1985).[12] Although Tri-Solgen was widely used in

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[11] See Kathryn M. Edwards & Michael D. Decker, *Pertussis vaccines*, in VACCINES 467, 485 ("Edwards & Decker") ("For some time, there was substantial suspicion that whole-cell vaccines might be causally related to devastating outcomes such as encephalopathy or sudden infant death syndrome (SIDS), *but several careful epidemiologic studies have largely dispelled these concerns*.") (emphasis added).

[12] The internal Lederle study Petitioners cite (Br. 18) that compares Lederle's vaccine to Lilly's (J.A. 230-34) is not to the contrary. All of the observed reactions were local, not severe.

the 1960s, Eli Lilly withdrew it in the 1970s, and it was never licensed again.

Nor, contrary to Petitioners' suggestion (Br. 19), were acellular pertussis vaccines an available alternative as of 1992 for U.S. children under two years old. Acellular vaccines use characterized and purified parts of the pertussis bacterium to stimulate an immune response.[13] Petitioners point to Japan's licensure of acellular pertussis vaccines in the 1980s for use in infants *two years of age and older*. But that licensure occurred under circumstances that could not occur under the U.S. regulatory system: in the face of an epidemic of whooping cough, the Japanese government permitted acellular pertussis vaccines to go to market with no efficacy testing and only limited clinical studies of the vaccine's safety and ability to provoke an immune response. J.A. 97-98.[14]

FDA licensing of an acellular pertussis vaccine for use in the United States, by contrast, required thorough scientific research, properly designed clini-

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See J.A. 232; see also *Toner v. Lederle Labs.*, 779 F.2d 1429, 1431 (9th Cir. 1986) (Kennedy, J.) (noting that the Lederle internal study "found fewer local reactions associated with Tri-Solgen, but it noted no severe reactions in either cohort due to the restricted number of subjects studied").

[13] "Characterized" refers to identifying the specific component parts of the cell and their biological activity. A "purified" vaccine uses only those parts of the cell believed to stimulate an immune response.

[14] The epidemic, involving more than 13,000 illnesses and 41 deaths, occurred after a steep drop in immunization rates arising from public reaction to media coverage of two infant deaths within 24 hours of receiving a whole-cell DTP vaccination in 1974 and 1975. See E.J. Gangarosa *et al.*, *Impact of anti-vaccine movements on pertussis control: the untold story*, 351 Lancet 356, 357-58 (Jan. 31, 1998); J.A. 97.

cal trials on all relevant age groups, and completion of the FDA regulatory process. For the clinical trials, vaccine manufacturers were permitted to take into account the Japanese experience of administering acellular pertussis vaccine to children two years of age and older. Based in part on studies of that experience, in December 1991, FDA licensed Lederle's ACEL-IMUNE® DTaP vaccine for use as the fourth and fifth doses of the recommended DTP series for children over two years old who had previously been immunized with three or four doses of whole-cell DTP vaccine. J.A. 101.

But as of 1992 (the time of the vaccination at issue in this case), the efficacy of acellular pertussis vaccines in children under two years old had yet to be proven in any clinical trial, and it was not yet known whether acellular vaccine would be as safe and effective for children under two years old as whole-cell vaccine had proven to be over decades of use. J.A. 100-01. To demonstrate the safety and effectiveness of the acellular vaccine for use in children under two years old, nine large-scale clinical efficacy trials were conducted in Europe and Africa involving eleven different acellular pertussis vaccines manufactured by a number of different entities. Edwards & Decker at 489-501.[15] FDA did not approve an acellular pertussis vaccine for use in children under two years old until July 31, 1996. J.A. 33-34.

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[15] One clinical trial specifically focused on an acellular pertussis vaccine developed by the U.S. government. That acellular vaccine was not approved until 1998. Edwards & Decker at 499; CDC, *FDA Approval of a Fourth Acellular Pertussis Vaccine for Use Among Infants and Young Children*, 47 MMWR 934 (Nov. 6, 1998).

E. Proceedings Below

On April 3, 1995, Petitioners filed a Vaccine Court petition seeking compensation for injuries Hannah Bruesewitz allegedly suffered as the result of a DTP vaccination administered in April 1992. Specifically, Petitioners alleged that Hannah has been diagnosed with "residual seizure disorder" and "developmental delay"—non-Table injuries for DTP vaccines. After an evidentiary hearing, Vaccine Court dismissed their petition with prejudice for failing to establish that the DTP vaccine caused Hannah's injuries. *Bruesewitz* v. *Sec'y of HHS*, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Dec. 20, 2002). Notwithstanding the denial of the petition, Vaccine Court later awarded Petitioners over $126,000 in attorneys' fees and costs. J.A. 3.

Petitioners rejected Vaccine Court's judgment as to their underlying claims pursuant to Section 21(a) of the Vaccine Act, 42 U.S.C. 300aa-21(a), and filed this *de novo* action, see *id.* 300aa-23(e), against Respondent Wyeth (as successor to American Cyanamid) in Pennsylvania state court in October 2005, asserting claims for design defect (under negligence and strict-liability theories), failure to warn, and manufacturing defect. Respondent removed the action to federal court and moved for summary judgment. After "extensive discovery" (App. 54),[16] the district court granted summary judgment to Respondent on Petitioners' entire complaint. App. 53-99. The district court ruled, *inter alia*, that Section 22(b)(1) of the Vaccine Act expressly preempts Petitioners' design-defect claims. App. 82-87. The court also ruled that Petitioners had failed to raise a genuine issue of

[15] References to "App." are to the petition appendix.

material fact on either their manufacturing-defect claim or their failure-to-warn claim. On the latter claim, the court found that Petitioners had failed to overcome the statutory presumption that Respondent's FDA-approved warnings were proper because they could not show that Respondent had withheld information from FDA or otherwise failed in any regulatory compliance. App. 88-98.

The Third Circuit affirmed. App. 1-52. As to the design-defect claim, the Circuit held that the claim is preempted by Section 22(b)(1), reasoning that the statutory text, structure, and legislative history showed "a 'clear and manifest' expression of congressional intent" to preempt design-defect claims. App. 30. The Circuit observed that Petitioners' construction of the statute, by allowing design-defect claims to be litigated on the merits in virtually every case, would trigger the "very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act." App. 36.[17]

SUMMARY OF ARGUMENT

Congress enacted the Vaccine Act against a backdrop of increasing design-defect litigation against manufacturers, the exit of some manufacturers from the industry, and a consequent shortage of DTP vaccine. The Act's express preemption provision, Section 22(b)(1), addresses these concerns by preempting state-law tort claims with the exception of

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[17] The Third Circuit also affirmed the grant of summary judgment to Respondent on the failure-to-warn and manufacturing-defect claims. App. 43-52. Petitioners did not seek this Court's review of those aspects of the Third Circuit's decision. See Pet. i (addressing only design-defect claim).

two specific carve-outs—failure "properly [to] prepare" the vaccine and failure to "accompan[y] [the vaccine] by proper directions and warnings." Design-defect claims are not carved out from preemption, and any interpretation of the Act that would allow them to be asserted would frustrate Congress's purpose in enacting the Act.

I

The plain text of Section 22(b)(1) categorically preempts design-defect claims. This conclusion is corroborated by the structure of the Vaccine Act, and is fully consistent with Restatement (Second) of Torts § 402A, comment k (1965).

A

Section 22(b)(1) broadly preempts state-law tort claims, and then carves out from this preemption manufacturing-defect claims and certain failure-to-warn claims, but *not* design-defect claims. The statute does so by providing for preemption "if the [vaccine-related] injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." In other words, only if the injury or death could have been "avoided" by "prope[r] prepara[tion]" or "proper directions and warnings" may a state-law tort claim be asserted.

Petitioners unpersuasively seek to avoid the plain statutory text by frequently paraphrasing the statute to omit the key modifying phrase that follows the word "unavoidable." And Petitioners' interpretation, by allowing design-defect claims to proceed through trial and putting manufacturers to the expense of establishing case by case that their vaccines employed the safest design, would provide no protection

to manufacturers beyond that which was already provided by state law before the Vaccine Act.

B

The broader structure of the Vaccine Act strongly reinforces the import of the plain text of Section 22(b)(1). Specifically, other provisions of the Act achieve through regulation the incentive and compensation goals that would otherwise be met by the tort system.

First, as to incentives, the Vaccine Act established a National Vaccine Program that mandates that HHS promote and assure the development of safer vaccines. Congress understood that the complex balancing of public benefits to society against the rare side effects of certain vaccines was best performed by expert federal agencies with a national, public-health perspective rather than by lay juries, sitting in individual cases, that would tend to focus on the alleged side effects of vaccines in disproportion to the indisputable benefits that vaccines provide to parties not before the court. To assist in monitoring existing vaccines and developing ever better ones, the Act strongly encourages manufacturers to disclose adverse events from vaccines by conditioning the preemption of failure-to-warn claims on the manufacturer's reporting of such events to FDA both before and after licensure of the vaccine. And, even before licensure, proposed vaccine designs are subjected to more comprehensive clinical trials than are ordinary drugs or medical devices.

Second, as to compensation, the Vaccine Act counterbalances Section 22(b)(1)'s preemption of design-defect civil claims by providing a generous, no-fault administrative compensation scheme. This scheme

does not require claimants to prove that their injuries resulted from a design defect. To date, this compensation scheme has awarded total compensation of over $1.8 billion, or an average of more than $750,000 to each petitioner who received an award. This scheme distinguishes cases such as *Wyeth* v. *Levine*, 129 S. Ct. 1187, 1199 (2009), where this Court found the absence of such an administrative compensation scheme to undermine the defendant's assertion of preemption.

C

Petitioners rely heavily on the incorrect notion that Section 22(b)(1) *codified* Restatement (Second) of Torts § 402A, comment k. They assert that Congress embraced the view of *some* courts regarding Comment k before the Act that manufacturers could escape strict liability only by demonstrating case by case that their vaccine employed the safest feasible design.

Petitioners' reliance on Comment k is unpersuasive. Congress did not codify Comment k insofar as Comment k speaks only to a defense to strict-liability claims, whereas Section 22(b)(1) is much broader. Section 22(b)(1) preempts *any* "civil action for damages" (including claims for negligence and breach of implied warranty in addition to strict liability)—unless the claim presented falls within the carve-out for manufacturing-defect and certain failure-to-warn claims. Moreover, Comment k is part of a restatement of the common law of torts, whereas Section 22(b)(1) is part of a comprehensive federal scheme (applicable only to a small number of products, childhood vaccines) that achieves through regulatory means the incentive and compensation goals of tort law.

Even if these differences between Comment k and Section 22(b)(1) could be ignored, Comment k does not assist Petitioners because state courts were deeply divided on its interpretation as of the Vaccine Act's enactment in 1986. Some state courts treated Comment k's protection against design-defect claims as categorically available to approved vaccines and drugs. Others treated such protection as conditional on the manufacturer's showing that it employed the safest design.

II

Although the plain text of Section 22(b)(1) and the structure of the Vaccine Act make it unnecessary to consult legislative history, the most authoritative piece of that history, the House Energy Committee Report from the 1986 Congress that enacted the Act, further confirms that Congress intended categorically to preempt design-defect claims. Directly addressing the question presented in this case, the Report explained that, "if [claimants] cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings[,] [they] should pursue recompense in the compensation system, not the tort system."

The 1986 House Report is not trumped by a 1987 report issued in connection with funding the Vaccine Act's compensation program, a measure undertaken by a subsequent Congress. The 100th Congress made no substantive change to provisions, including Section 22(b)(1), that had already been enacted by the 99th Congress in 1986.

III

Congress's concern that allowing design-defect claims against manufacturers would potentially jeopardize the vaccine supply is just as applicable today as it was in 1986. The number of vaccine manufacturers has not increased since then, and the threat that design-defect claims will be asserted against those few manufacturers continues to be substantial. Some 5,000 petitions alleging a supposed causal link between vaccines and childhood autism are currently pending in Vaccine Court. No scientific support for either of two causation theories has been found in any of the six autism test cases tried to date. Vaccine Court petitioners faced with such adverse results might well bring a crushing wave of state-law claims, including design-defect claims, if Section 22(b)(1) is interpreted not to preempt them.

Experience under the Vaccine Act since its enactment has shown that the Act has succeeded in accomplishing through regulatory means the incentive and compensation goals of the tort system. Over twenty new childhood vaccines have been brought to market since the effective date of the Act; adverse events are promptly reported to the government under the VAERS system; and over $1.8 billion in compensation has been awarded to petitioners by Vaccine Court. Thus, no policy consideration supports restricting the scope of the preemption provision that Congress enacted in 1986.

ARGUMENT

I. THE VACCINE ACT'S PLAIN TEXT PREEMPTS VACCINE DESIGN-DEFECT CLAIMS, AND THE ACT'S STRUCTURE SUPPORTS THIS CONCLUSION

Petitioners assert that Section 22 leaves virtually unchanged the full range of state tort claim opportunities available to plaintiffs before enactment of the Vaccine Act. On Petitioners' view, Section 22(b)(1) allows juries to decide, case by case, that vaccine designs whose safety and efficacy have merited federal government approval for nationwide use are nonetheless defective and should not be on the market. Such a reading is untenable. Section 22(b)(1), by its terms, precludes all state-law tort claims except manufacturing-defect claims and those failure-to-warn claims in which a plaintiff can rebut the statutory presumption in Section 22(b)(2). Section 22(b)(1) thus precludes design-defect claims such as the ones brought here.

Petitioners' argument is likewise belied by the structure of the Vaccine Act, which establishes a comprehensive federal scheme for approving and monitoring existing vaccines and promoting research and development of better ones, and which provides a generous program of no-fault compensation to victims of vaccine side effects.

Petitioners' attempt to draw support from Restatement (Second) of Torts § 402A, comment k is unpersuasive. Congress looked to Comment k for the principle that some products are categorically not defective if properly prepared and accompanied by proper directions and warnings, and treated routine childhood vaccines as such products. Petitioners offer

no explanation why Congress would have intended state tort law, whose disastrous effects on the vaccine supply Congress was intent on averting through passage of the Vaccine Act, to displace standards set by a national vaccine program that was designed "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1.

A. Section 22(b)(1)'s Text Expressly Preempts Design-Defect Claims While Preserving Manufacturing-Defect And Failure-To-Warn Claims

Section 22(b)(1) expressly preempts state law otherwise applicable to vaccine-related injury claims under 42 U.S.C. 300aa-22(a) ("Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death."). Section 22(b)(1) provides:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. 300aa-22(b)(1).

The word "unavoidable" is immediately modified by the phrase "even though the vaccine was properly prepared and was accompanied by proper directions and warnings." *Ibid.* Section 22(b)(1) thus provides

for preemption except in cases where the claimed side effect would have been "avoided" if the vaccine had been "properly prepared" or "accompanied by proper directions and warnings." Section 22(b)(1) does *not* provide that a side effect might be "avoided" if a vaccine had been "properly designed."

Congress's choice of the definite article, "*the* vaccine," 42 U.S.C. 300aa-22(b)(1) (emphasis added), is consistent only with a reading that preserves manufacturing-defect and failure-to-warn claims, not design-defect claims. "*The* vaccine" refers to the vaccine that was actually administered and is alleged to have caused the vaccine-related injury or death for which the manufacturer is being sued. As to that administered vaccine, a manufacturer may be found liable for manufacturing defect if it did not adhere to the vaccine's FDA-approved specifications, or for failure to warn if the manufacturer did not comply with regulatory requirements or withheld information from FDA.

In carving out from preemption some claims concerning "*the* vaccine" that was actually administered, Congress recognized that proper manufacturing and labeling are within the manufacturer's exclusive control. By contrast, vaccine manufacturers do *not* have discretion to change the design of a vaccine; to do so creates a new vaccine that must be separately approved by FDA after extensive clinical trials. The Vaccine Act leaves assessment of any risks inherent in a vaccine's *design* to a carefully wrought federal regulatory process. It permits civil juries to decide whether a manufacturer defectively produced, or failed to accompany with appropriate warnings, *the* vaccine that was actually administered; but the Act forecloses juries from assessing whether the federal

regulatory process should have approved *a* different, allegedly safer vaccine design.

To avoid the simple and straightforward reading of the text of Section 22(b)(1) that limits the preemption carve-out to manufacturing-defect and failure-to-warn claims, Petitioners repeatedly omit from their quotations of that subsection the fifteen words that follow the word "unavoidable," starting with "even though ...." *E.g.*, Br. 25, 29. Those fifteen words, however, are crucial to the meaning of the clause. Had Congress intended to allow claims that a vaccine side effect was avoidable through an alternative design, it would have stopped the clause at the word "unavoidable." It did not. Moreover, the logical and concise way for Congress to embody Petitioners' view would have been to end the preemption provision with the words "unavoidable side effects." That Congress instead selected the language "side effects that were unavoidable even though ...," is a textual indication that the words following the term "unavoidable" are the key to understanding the entire phrase "side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions."

When Petitioners do acknowledge the words that follow and explicate the word "unavoidable," they assert (Br. 38) that those words merely impose additional prerequisites to preclusion of a lawsuit under Section 22(b)(1) on top of the supposed requirement that the manufacturer show that the vaccine employed the safest design. But to support such a reading, Petitioners must twist the order of the words in the statute and draw on the subsection's heading ("Unavoidable adverse side effects; warnings") so that the statute's actual text, "side effects that were

unavoidable even though ...," is rephrased as "unavoidable side effects even though ...." This misconstrues the subsection's text and misuses its heading, which merely makes a short-form reference to the clear statutory text.[18]

Petitioners contend that it is Respondent that does not give meaning to all the words contained in Section 22(b)(1), arguing that, under Respondent's interpretation, Section 22(b)(1) would read the same way if the conditional phrase "if the injury or death resulted from side effects that were unavoidable" were removed. Br. 39-40. But that is not the case, as then the statute would provide that "[n]o vaccine manufacturer shall be liable in a civil action for damages ... *even though* the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1) (emphasis added).[19] It makes no sense to read the statute to absolve a manufacturer of liability "even though" it does everything correctly. It does, however, make sense to address side effects that could not have been avoided through proper warnings and manufacturing, and the statute does so by preempting tort claims arising out of vaccine-related injuries that occurred even though the vaccine was properly manufactured and had proper warnings. Only Respondent's reading gives effect to *all* the words in the sentence.

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[18] As this Court held regarding another section of the Vaccine Act, "even if the language of the heading did conflict with the text ..., the latter would prevail, since the table heading was obviously meant to be a short form of the text preceding it." *Whitecotton*, 514 U.S. at 274.

[19] Petitioners drop the italicized words "even though" from the statute in their "plain text" argument. See Br. 39.

By effectively stopping the sentence after the word "unavoidable," Petitioners' interpretation would render Section 22(b)(1) meaningless, merely perpetuating the status quo *ante* the Vaccine Act. On Petitioners' reading, manufacturers would face design-defect claims as well as manufacturing-defect and failure-to-warn claims under state law, now just as they did before the Vaccine Act, and could obtain design-defect "preemption" only *after* defending each case on the merits. Moreover, if read as Petitioners propose, Section 22(b)(1) would preempt design-defect claims only under circumstances where the manufacturer would already have won the case on state-law grounds. No State in 1986 imposed (or today imposes) design-defect liability on manufacturers for injuries that could not have been avoided under any circumstances. Thus, on Petitioners' reading, Section 22(b)(1)'s express limitation on civil liability would be superfluous.

Petitioners also place heavy reliance (Br. 32, 35-36) on the word "if," arguing that its conditional nature must mean that Congress intended a case-by-case inquiry into whether a vaccine's side effects were "unavoidable" because the vaccine could have employed a safer design. But the word "if" cannot bear the weight Petitioners assign to it. The natural meaning of the term "if" here simply allows inquiry into whether the side effects at issue were "avoidable" under either of the two circumstances enumerated in Section 22(b)(1)—by "properly prepar[ing]" the administered vaccine or by accompanying that vaccine with "proper directions and warnings."

Finally, Petitioners argue (Br. 36-37) that Congress cannot have meant to preempt design-defect claims because it failed to provide a presumption that FDA-

approved designs are proper along the lines of the presumption set forth in Section 22(b)(2) that FDA-approved warnings are proper. But imposing limits, via a rebuttable presumption, on a failure-to-warn claim that is not preempted cannot suggest that a different claim (design defect) is itself not categorically preempted. The straightforward way to read Section 22(b) as a whole is that it allows civil liability for manufacturing-defect claims without limitation; allows civil liability for failure-to-warn claims limited by the rebuttable presumption that FDA-approved warnings are proper; and categorically preempts all other claims, including design-defect claims.[20]

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[20] Petitioners also point to another statute, 42 U.S.C. 247d-6d ("PREP Act"), in support of their construction of Section 22(b)(1), but this analogy is strained. The PREP Act is irrelevant here. First, it sheds no light on Congress's intent in enacting Section 22(b)(1) because it was enacted some 19 years after the Vaccine Act, for different reasons and under different circumstances. See *Halverson* v. *Slater*, 129 F.3d 180, 186 (D.C. Cir. 1997) (declining to draw inference from different language in statute enacted seven years after enactment of statute at issue). Second, the PREP Act covers vaccines that the Secretary of HHS has deemed necessary to respond to public health emergencies, not the vaccines recommended for routine administration to children covered by Section 22. See 42 U.S.C. 300aa-14(e), 22(b). Third, the PREP Act grants nearly complete legal immunity to manufacturers of the vaccines it covers, while the Vaccine Act balances limitations on civil liability with a no-fault administrative compensation scheme for vaccine-injured persons.

B. The Structure Of The Vaccine Act, By Promoting Safe And Efficacious Vaccines While Providing Administrative Compensation, Confirms That Section 22(b)(1) Preempts Design-Defect Claims

The overall structure of the Vaccine Act reinforces the textual argument that Section 22(b)(1) preempts all design-defect claims. The structure of the Vaccine Act reflects a determination to change the status quo regarding the research, development, manufacturing, and testing of childhood vaccines. The Act also instituted a generous administrative scheme to provide compensation for vaccine injuries that otherwise would have been sought under state tort law.

First, the Vaccine Act established a National Vaccine Program that, unlike any program applicable to ordinary drugs or any program that previously existed for vaccines, mandates that HHS promote, make, and/or assure the development of safer vaccines. 42 U.S.C. 300aa-27(a). The Act ensures that expert federal agencies and advisory committees with a systemic national perspective, not civil juries judging individual claims, will make decisions on appropriate vaccine design. As this Court has observed generally in the area of medical products, "[a] jury ... sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 325 (2008).

This is exponentially true in the vaccine context, where, "even though vaccines themselves cause a small number of serious injuries or deaths, their widespread use dramatically reduces fatalities." *Schafer* v. *Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir.

1994) (Breyer, C.J.); see also *ibid.* ("[T]he polio vaccine may itself cause about five annual incidents of paralysis. But, before widespread vaccination, ... polio injured, paralyzed, or killed about 57,000.") (citations omitted). Were the relatively few victims of vaccine side effects permitted unfettered resort to civil litigation before lay juries, adverse side effects would assume disproportionate salience and the vital social benefits of vaccines to the nation's population would be discounted. Thus, to achieve the best vaccine design, Congress chose administrative regulation over tort law, mandating that the determination of which vaccine design "achieve[s] the optimal prevention of human infectious diseases ... *and* ... achieve[s] optimal prevention against adverse reactions to vaccines," 42 U.S.C. 300aa-1 (emphasis added), be made by HHS and FDA, not case by case by juries or judges under a patchwork of state tort laws.

The Vaccine Act's forward-looking research program is supplemented by the powerful incentives imposed upon manufacturers by Section 22(b). Specifically, by allowing failure-to-warn claims if a plaintiff can overcome the presumption set forth in Section 22(b)(2), and by allowing manufacturing-defect claims generally, Section 22(b) strongly encourages vaccine manufacturers to control risks related to the manufacture and administration of a particular vaccine and thus that are within their exclusive power to control. The carve-out for manufacturing-defect claims gives manufacturers a strong incentive to make vaccines according to their FDA-approved specifications. The carve-out for limited failure-to-warn claims gives manufacturers a strong incentive to comply with all regulatory requirements and to make full disclosure of information (including

adverse events) to FDA.[21] But Section 22(b)(1) bars all other state-law civil actions, declining to allow judges and juries to look beyond the production and administration of a particular FDA-approved vaccine to assess whether a supposed alternative, safer vaccine theoretically might have been designed—an area beyond the exclusive control of any manufacturer in such a closely regulated federal system. See U.S. *Ferrari* Br. 15 ("The tort system—in which juries may pay little heed to this social cost/benefit calculus ... —is poorly equipped to encourage optimally safe and effective vaccines.")

Congress's decision to allow claims for manufacturing-defect and certain failure-to-warn claims is consistent with this predominantly regulatory scheme. Vaccine design involves complex policy decisions balancing safety and efficacy, and allowing juries to make such decisions would produce varying decisions in different States about whether any given vaccine design is defective and thus should be removed from the market.[22] By contrast, nationwide public health policy choices are not presented in litigation over whether an individual lot of vaccine was manufactured according to its FDA-approved design, or whether a manufacturer has complied with appli-

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[21] Section 22(b)(2) thus provides an alternative means of serving a traditional goal of pharmaceutical tort litigation: to "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." *Wyeth* v. *Levine*, 129 S. Ct. at 1202.

[22] This Court has previously recognized that jury verdicts powerfully affect the conduct of manufacturers. *Riegel*, 552 U.S. at 325 ("State tort law that requires a manufacturer's [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.").

cable regulations and provided FDA with all required information before and after a vaccine's licensure so as to enjoy presumptive protection from failure-to-warn claims under 42 U.S.C. 300aa-22(b)(2). Further reflecting the importance of having expert scientists rather than juries weigh the public benefits of vaccines against the cost of their rare side effects, manufacturers are absolutely barred from changing the design of an approved vaccine without prior governmental approval. This feature of the vaccine regulatory scheme distinguishes the warning at issue in *Wyeth* v. *Levine*, which could be changed before approval under a "changes being effected" (CBE) provision. 129 S. Ct. at 1196-99.

Second, reflecting Congress's awareness that limiting the liability of manufacturers would limit the ability of injured parties to recover, the Vaccine Act created a no-fault compensation scheme, 42 U.S.C. 300aa-11-17, in which petitioners may receive generous recoveries in Vaccine Court without having to prove any design defect. In the two decades of its operation, Vaccine Court has awarded total compensation of over $1.8 billion, or an average of over $750,000 to each petitioner that has received an award. This administrative compensation scheme distinguishes *Wyeth* v. *Levine* and other cases where this Court found that the absence of an alternative to compensation under tort law weighed against federal preemption. See 129 S. Ct. at 1199 ("Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment."); *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment,

remove all means of judicial recourse for those injured by illegal conduct").[23]

C. Restatement (Second) Of Torts § 402A, Comment k Is Consistent With The Text And Structure Of The Act In Categorically Precluding Design-Defect Claims

Unable to find in the text or structure of the Vaccine Act any congressional purpose to preserve case-by-case adjudication of supposed vaccine design defects under state law, Petitioners rely heavily on Comment k to Restatement (Second) of Torts § 402A. Br. 29-33, 37, 39, 41, 45-46. Comment k, drafted in 1965, provides that an "[u]navoidably unsafe product[]" may not be subjected to a strict-liability claim so long as it is "properly prepared, and accompanied by proper directions and warning":

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified,

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[23] Additionally, the scope of the preemption here affects far fewer products than in other recent pharmaceutical preemption cases. Only twelve categories of childhood vaccines will be affected by this Court's ruling here, a fraction of the 11,000 FDA-approved products to which preemption would have applied in *Wyeth* v. *Levine*, 129 S. Ct. at 1202.

> notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician....

RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k.

Petitioners argue that Section 22(b)(1) of the Vaccine Act "expressly codified" Comment k. Br. 32. That is demonstrably incorrect. Restatement § 402A, to which Comment k is appended, addresses only actions for *strict liability*. Section 22(b)(1), by contrast, is far broader, preempting *any* "civil action for damages"—including claims for negligence, breach of implied warranty, and all other causes of action regarding vaccines manufactured properly and accompanied by proper directions and warnings.

Moreover, while Comment k arises from the common law of torts, Section 22(b)(1) is part of a comprehensive federal regulatory scheme that provides for heavy governmental involvement in research and development, approval and monitoring of vaccines to ensure their safe and efficacious production, and a no-fault compensation program for victims of vaccine-related side effects. Cf. *Toner* v. *Lederle Labs.*, 828 F.2d 510, 514 (9th Cir. 1987) (Kennedy, J.) (in pre-Vaccine Act case, applying Idaho law allowing a negligent design-defect claim against vaccine manufacturer, while noting that "[w]ere we charged with deciding whether jury verdicts are the most sensible way of allocating risks and costs regarding vaccines that have been proved beneficial, we might well

design a different method"). And while Comment k is not confined to any particular type of product, Section 22(b)(1) applies exclusively to the small number of childhood vaccines covered by the Vaccine Act and vital to public health programs.

Although Section 22(b)(1) did not codify Comment k, it looked to "the principle of Comment k,"[24] which is that certain products are not defective because their social utility outweighs their inherent risk. Such products are categorically not subject to strict liability, provided they are properly manufactured and are accompanied by adequate warnings. Section 22(b)(1) is best read as a determination that all routinely administered FDA-approved childhood vaccines are categorically deserving of protection against all tort liability (not just strict liability) arising out of risks inherent in the vaccine, as long as they are "properly prepared" and "accompanied by proper directions and warnings."

Petitioners look to certain pre-Vaccine Act decisions interpreting Comment k to interpret Section 22(b)(1). This interpretive method is flawed because of the significant differences noted above between Section 22(b)(1) and Comment k. But even if those differences were ignored, Petitioners' argument can have no force unless the pre-Vaccine Act cases pointed clearly in the direction of case-by-case analysis of design-defect claims. They did not. The courts were deeply divided on this issue, and thus

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[24] As discussed *infra*, at 47-48, the legislative history does not show that Congress intended to "codif[y] comment k." Pet. Br. 13. Rather, the 1986 House Report stated that Section 22(b)(1) "sets forth the *principle* contained in" Comment k. 1986 House Report at 26 (emphasis added); see also App. 33-36 (Third Circuit opinion).

Petitioners are unaided by the fact that *some* courts as of 1986 interpreted Comment k to put manufacturers to a case-by-case showing that their products were unavoidably unsafe, see, *e.g.*, *Feldman* v. *Lederle Labs.*, 479 A.2d 374, 383-84 (N.J. 1984); Pet. Br. 33-34 & n.17. Numerous *other* courts interpreting state law as of 1986 categorically precluded design-defect claims against products like vaccines whose overwhelming social utility makes them appropriate to market even though they carry some inherent risk.[25] Petitioners offer no reason to sup-

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[25] See, *e.g.*, *Lindsay* v. *Ortho Pharm. Corp.*, 637 F.2d 87, 90 (2d Cir. 1980) (stating that, under New York law, prescription drugs are deemed "unavoidably unsafe products"); *Raynor* v. *Richardson-Merrell, Inc.*, 643 F. Supp. 238 (D.D.C. 1986) (stating that, under District of Columbia law, drugs are unavoidably unsafe products); *Brown* v. *Superior Court*, 227 Cal. Rptr. 768 (Cal. Ct. App. 1986) (rejecting case-by-case approach to Comment k in context of prescription drugs and affirming trial court's ruling that "design defect theory is not available for injury alleged to have been caused by a prescription drug"), *aff'd*, 751 P.2d 470, 481-83 (Cal. 1988) (holding that all prescription drugs are unavoidably unsafe under Comment k); *Stone* v. *Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984) (all drugs and vaccines are within the scope of Comment k); *Baldino* v. *Castagna*, 478 A.2d 807, 810 (Pa. 1984) (stating that a prescription drug manufacturer is not strictly liable if the drug is properly prepared and labeled); *McKee* v. *Moore*, 648 P.2d 21, 23 (Okla. 1982) (stating that prescription drugs and devices are "unavoidably unsafe products"); *McDaniel* v. *McNeil Labs. Inc.*, 241 N.W.2d 822, 828 (Neb. 1976) (concluding that FDA approval precludes finding that a drug is unavoidably unsafe unless the manufacturer submitted inaccurate, incomplete, misleading, or fraudulent information in approval process), overruled by *Freeman* v. *Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000); *Lewis* v. *Baker, Richardson-Merrell, Inc.*, 413 P.2d 400, 404 (Or. 1966) (same), overruled in part on other grounds, *McEwan* v. *Ortho Pharm. Corp.*, 528 P.2d 522 (Or. 1974). See generally *Militrano* v. *Lederle Labs.*, 769

pose that Congress intended to adopt one rather than the other strand of divided state common law.

Moreover, as the Third Circuit correctly found (App. 29-30), Petitioners' reading of Section 22(b)(1), by virtue of Section 22(e) (preempting state laws that "prohibit[t] an individual from bringing a civil action ... if such civil action is not barred by this part"), would have the perverse consequence of leaving vaccine manufacturers *worse off* under state law than they were before the Vaccine Act. Under Petitioners' approach, those States with statutes providing categorical Comment k protection to all vaccines would now have to *allow* case-by-case adjudication of design-defect claims in cases covered by the Vaccine Act. Such an outcome cannot be squared with the Act's genesis in congressional concern that the litigation burden on manufacturers was so severe that it threatened the nation's vaccine supply.

D. The Presumption Against Preemption Has No Bearing On This Case

This Court has described the presumption against preemption as a tiebreaker. See *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005) ("[E]ven if [the reading favoring preemption] *were just as plausible* as our reading of that text—we would nevertheless have a duty to accept the reading that disfavors pre-emption.") (emphasis added). The presumption has no bearing on this case, however, because the case is not in need of a tiebreaker. Congress's intent to preempt vaccine design-defect

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N.Y.S.2d 839, 844-45 (N.Y. Sup. Ct. 2003) ("[W]hile some courts concluded that a case-by-case analysis was necessary ... others concluded that prescription drug manufacturers were generally not liable for design defect claims.").

claims is clear from the text of Section 22(b)(1), and Petitioners' construction of that text is not "as plausible" as Respondent's.

Invocation of the presumption is likewise inappropriate here because *both* parties' proposed interpretations of Section 22(b)(1) would result in some preemption of state law. Under Respondent's reading of Section 22(b)(1), state law would be preempted in those States that allow case-by-case inquiry into the safety of a vaccine's design before conferring Comment k protection. But if Petitioners' reading of Section 22(b)(1) were accepted, then, by virtue of Section 22(e), there would be preemption of state law in those States with statutes providing Comment k protection to all vaccines. Where either party's position will displace some States' existing law, the federalism principle embodied in the presumption against preemption cannot serve as a tiebreaker.

II. THE LEGISLATIVE HISTORY CONFIRMS THAT SECTION 22(b)(1) PREEMPTS DESIGN-DEFECT CLAIMS

Because the text of Section 22(b)(1) and the structure of the Vaccine Act demonstrate Congress's intent to preempt state-law design-defect claims arising from vaccine-related injuries, the Vaccine Act's legislative history need not be consulted, but if consulted, that history confirms Respondent's and the Third Circuit's interpretation.

A. The 1986 House Committee Report Affirmed That Vaccine Injuries Other Than Those From Manufacturing Or Warning Defects Should Receive "Recompense In The Compensation System, Not The Tort System"

H.R. Rep. No. 99-908, prepared in 1986 in support of the Vaccine Act by the Committee on Energy and Commerce (the "1986 House Report"), provides "the authoritative source for finding the Legislature's intent." *Garcia* v. *United States*, 469 U.S. 70, 76 (1984) ("Committee Reports on the bill, ... '[represent] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.'") (quoting *Zuber* v. *Allen*, 396 U.S. 168, 186 (1969)). Accord, *Eldred* v. *Ashcroft*, 537 U.S. 186, 210 n.16 (2003). The 1986 House Report sets out the rationale for the Vaccine Act and the compensation program, expresses concern that state tort liability will undermine vaccine manufacturers and the nation's vaccine supply, and expresses Congress's intent that the Act's preemption clause be read broadly to preempt state law actions like the one here.

As the Committee explained, "in light of the availability of a comprehensive and fair compensation system," the Vaccine Act established standards of responsibility for manufacturers that were designed to lessen their potential liability for vaccine-related injuries. 1986 House Report at 25. Directly addressing the question presented in this case, the 1986 House Report explains:

> Given the existence of the [no-fault] compensation system in this bill, ... [v]accine-injured persons will now have an appealing alternative to

> the tort system. Accordingly, *if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.*

Id. at 26 (emphasis added). Thus, the 1986 House Report makes clear that the Vaccine Act differentiates manufacturing-defect and failure-to-warn claims from other claims, including design-defect claims, and allows persons alleging vaccine-related injuries to pursue tort claims under only the former two theories.

In preempting other claims, the Committee recognized that, by the mid-1980s, the "great difficulty in obtaining insurance ... coupled with the possibility that vaccine-injured persons may recover substantial awards in tort claims ... prompted manufacturers to question their continued participation in the vaccine market." 1986 House Report at 6-7. The Committee further recognized that these circumstances had the potential to create a public health crisis, as the "withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children and, perhaps, a resurgence of preventable disease." *Id.* at 7. Through the Vaccine Act, the Committee sought to create "a more stable childhood vaccine market" by giving vaccine manufacturers "a better sense of their potential litigation obligations." *Ibid.*

The 1986 House Report also confirms that, contrary to Petitioners' assertions, Congress did not intend to "codif[y] comment k." Br. 13; see also *id.* at 32, 46-47. Instead, the 1986 House Report explains

that Section 22(b)(1) reflects the "principle" of Comment k. 1986 House Report at 26. Specifically, the 1986 House Report states that the Committee "intends that the principle in Comment K regarding 'unavoidably unsafe' products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, *apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.*" *Id.* (emphasis added). The Committee thus expressed the view that routinely administered childhood vaccines are *categorically* within "the principle of Comment k," and Petitioners are incorrect to suggest that the 1986 House Report can be read to require a "threshold" judicial determination, case by case, "that a vaccine's side effects ... [were] unavoidable." Br. 47.[26]

B. A 1987 House Committee Report Cannot Rewrite The Legislative History Of A 1986 Enactment

In the face of this clear indication of contemporaneous congressional intent in the 99th Congress, Petitioners invoke (Br. 50) passages in a 1987 committee report from the *100th Congress* regarding legislation providing appropriations for the Vaccine Act. See H.R. REP. NO. 100-391(I) (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1 ("1987 House Report"). The 1987 House Report states—contrary to the 1986

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[26] Petitioners also incorrectly assert that, "in discussing § 23(c) of the Act, the 1986 House Report confirmed that the *design* defect claims were not eliminated." Br. 46 (emphasis added). The Report actually referred to a "defective vaccine," without specifying that the defect related to design. 1986 House Report at 28. A vaccine could be "defective" based on a manufacturing defect or a failure to warn, the two theories explicitly enumerated as surviving preemption in Section 22(b)(1).

House Report—that the Vaccine Act was not intended "to preclude court actions under applicable law," and that the question "whether vaccines were unavoidably unsafe or not ... is left to the courts to determine." *Id.* at 691. The 1987 House Report also claims that the incorporation of Comment k into the Vaccine Act "was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe." *Ibid.*

The 1987 House Report, however, is not a proper guide to determining Congress's intent in enacting the Vaccine Act in 1986. As this Court recently explained, "[l]egislative history ... is considered persuasive by some, not because [such statements] reflect the general understanding of the disputed terms, but because the legislators who heard or read those statements presumably voted with that understanding." *District of Columbia* v. *Heller*, 128 S. Ct. 2783, 2805 (2008). Post-enactment statements, in contrast, "could have had no effect on the congressional vote." *Ibid.*; see also *id.* at 2837 n.28 (Stevens, J., dissenting) (post-enactment legislative history is "the least reliable source of authority for ascertaining the intent of any provision's drafters"). Cf. *Oscar Mayer & Co.* v. *Evans*, 441 U.S. 750, 758 (1979) ("'It is the intent of the Congress that enacted [the section] ... that controls.'") (quoting *Teamsters* v. *United States*, 431 U.S. 324, 354 n.39 (1977)).

Here, no Member of Congress could have relied on the 1987 House Report's statements about the Act in voting for it, including its preemption provision, in 1986. Rather, those Members who voted in favor of the Act did so with the understanding, expressed in the 1986 House Report, that vaccines that are properly manufactured and accompanied by proper

warnings "not be the subject of liability in the tort system." 1986 House Report at 26. This is so even though Section 22(b)(1) was not effective until the Compensation Fund was funded by the appropriations at issue in the 1987 House Report, as that appropriations bill did not modify or otherwise address the scope of a manufacturer's liability under the Act, which was settled in the 1986 legislation. See Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, Title IV, §§ 4301-07, 101 Stat. 1330 (1987).[27]

Thus, the statements in the 1987 House Report about the Committee's intent in enacting the express preemption provision in 1986—a subject not at issue in the 1987 amendments—is after-the-fact speculation and hearsay. This Court has viewed analogous *post hoc* attempts to amend a statute through legislative history with deserved suspicion. See, *e.g.*, *Exxon Mobil Corp.* v. *Allapattah Servs., Inc.*, 545 U.S. 546, 568, 570 (2005) (recognizing that, in some instances, "unrepresentative committee members—or, worse yet, unelected staffers and lobbyists—... attempt strategic manipulations of legislative history to secure results they were unable to achieve through the statutory text," and "refus[ing] to give any effect to [a *post hoc*] deliberate effort to amend a statute through a committee report").

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[27] Petitioners misleadingly assert, without citation, that the 1987 amendments, which were entitled the "Vaccine Compensation Amendments of 1987," modified several "substantive" provisions of the Act. Br. 51. The amendments addressed only the funding mechanism, the duration of a residual injury, awards of costs, the exhaustion requirement, and federal court jurisdiction. See Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, Title IV, §§ 4301-07, 101 Stat. 1330 (Dec. 22, 1987).

Nor does it avail Petitioners to rely (Br. 45-46) on the 1987 House Report's reference to a 1986 markup session in which the Committee purportedly rejected an express prohibition on design-defect claims. It is the Committee's contemporaneous report of the bill—not a preliminary mark-up session—that offers the authoritative guide to congressional intent. See, *e.g.*, *Garcia*, 469 U.S. at 76.

C. Other Pieces Of Legislative History Either Are Inconclusive Or Support Respondent's Position

Petitioners offer a hodgepodge of statements by individual Members of Congress, an Executive Branch official, and industry executives that they contend support their interpretation of Section 22(b)(1). None of these snippets, either individually or collectively, justifies disregarding the plain statutory language, confirmed by the 1986 House Report, indicating Congress's intent to preempt all claims against vaccine manufacturers other than manufacturing and warning claims.

Petitioners place surprising emphasis (Br. 47-48) on isolated floor comments and other statements regarding the Vaccine Act by Members of Congress. This Court, however, has long "eschewed reliance on the passing comments of one Member, and casual statements from the floor debates." *Garcia*, 469 U.S. at 76; see also *Weinberger* v. *Rossi*, 456 U.S. 25, 35 n.15 (1982) ("The contemporaneous remarks of a sponsor of legislation are certainly not controlling in analyzing legislative history."). This is particularly true of statements that post-date the enactment of a statute. See, *e.g.*, *Quern* v. *Mandley*, 436 U.S. 725, 736 n.10 (1978) ("[*P*]*ost hoc* observations by a single

member of Congress carry little if any weight."). Accord, *Heintz* v. *Jenkins*, 514 U.S. 291, 298 (1995).[28]

The testimony of industry witnesses cited by Petitioners (Br. 45, 49-50)—none of whom was referred to in the 1986 House Report—is even less relevant in discerning congressional intent. See, *e.g.*, *Kelly* v. *Robinson*, 479 U.S. 36, 51 n.13 (1986) ("[N]one of those statements was made by a Member of Congress, nor were they included in the official Senate and House Reports. We decline to accord any significance to these statements."). In any event, most of the cited testimony is either taken out of context or did not address the version of the bill that was ultimately enacted.

For instance, the statement by Lederle's president, Robert Johnson, in a 1986 subcommittee hearing that the bill would leave "open for litigation" claims "that the vaccines we sell are not as good as some alternative product" was made in response to a provision in H.R. 5184 that barred civil suits except where "the wrongful conduct of the defendant" was the basis of liability. 1986 Hearing at 238-39; National Childhood Vaccine Injury Act of 1986, H.R. 5184, 99th Cong., § 101(a) (1986) (§ 2122(c)(1)). But that provision was not part of the Vaccine Act as enacted. Similarly, Petitioners ignore that, during a 1987 subcommittee hearing, Mr. Johnson expressly

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[28] Likewise, contrary to Petitioners' intimations (Br. 48-49), post-enactment statements by executive officials on behalf of the President cannot show what *Congress* meant when it enacted legislation. Cf. Marc N. Garber & Kurt A. Wimmer, *Presidential Signing Statements As Interpretations Of Legislative Intent: An Executive Aggrandizement Of Power*, 24 HARV. J. LEG. 363 (1987) (arguing that courts should not use presidential signing statements to interpret statutes).

"disagree[d]" with any interpretation of the Act that would permit design-defect claims, explaining that Lederle "firmly believe[d] that this is exactly the opposite of what Congress intended." *Funding of the Childhood Vaccine Program: Hearing Before the Subcomm. on Select Revenue Measures of the H. Comm. on Ways and Means*, 100th Cong. 84-85 (1987).

In sum, the contemporaneous 1986 House Report, which offers the clearest and most authoritative guide to Congress's intent, confirms Congress's purpose to preempt all state-law claims against vaccine manufacturers other than manufacturing-defect and failure-to-warn claims. Petitioners may not rewrite that history by relying on an after-the-fact committee report or selective statements by Members or witnesses.

III. THE PURPOSE AND POLICY OF THE VACCINE ACT SUPPORT THE CATEGORICAL PREEMPTION OF DESIGN-DEFECT CLAIMS

Petitioners conclude their brief by arguing that their interpretation of Section 22(b)(1) serves Congress's purposes in enacting the Vaccine Act. These arguments are unpersuasive.

Petitioners first assert (Br. 52-54) that, without design-defect claims, manufacturers will lack sufficient incentive to develop new and improved vaccines. This assertion is not borne out by the development of new vaccines since the Act became effective. Over twenty new vaccines have been brought to market since enactment of the Vaccine Act in 1986. See *supra* at 28. This development cannot be attributed to potential tort liability for design-

defect claims, as no reported decision since 1986 in a case that is subject to the Vaccine Act has imposed liability against a vaccine manufacturer on the basis of a design-defect claim. Congress's comprehensive National Vaccine Program provides manufacturers with clear incentives to develop safe and efficacious vaccines without such tort liability.

Petitioners unpersuasively argue that vaccine-injury claimants need state-law tort liability in order to "uncove[r] information about adverse side effects not generally available to federal regulators." Br. 55. As an initial matter, there is no reason to think that manufacturers will have more information than federal regulators concerning adverse side effects, given that the complementary VAERS and VSD systems operate to provide substantial information on such side effects to federal regulators, and given that manufacturers' ongoing disclosure duties are enforced by conditioning the adequate-warnings presumption on manufacturers' compliance with those duties. But even if manufacturers could be assumed to have more information than federal regulators concerning adverse side effects, there is no basis to conclude that a *design*-defect claim (and the discovery that might come with it) is needed for plaintiffs to discover such information. Rather, plaintiffs may assert a manufacturing-defect or a failure-to-warn claim (the types of claims carved out from preemption under Section 22(b)(1)), and obtain discovery regarding adverse side effects through prosecution of those claims.

Petitioners further submit (Br. 58) that the requirement that injured persons must exhaust their Vaccine Court remedies and reject the resulting Vaccine Court judgment before bringing a civil action

may deter the claimant from bringing the civil action. But exhaustion affords manufacturers no reliable shield against having to litigate those claims where petitioners have no scientific basis for claiming causation; having lost in Vaccine Court, such petitioners have little to lose by forging ahead with a civil suit, however tenuous.

Finally, Petitioners speculate (Br. 59) that there is no real danger of vaccine manufacturers exiting the industry were design-defect claims allowed to be asserted in every case. This speculation, however, is belied by history. A deluge of cases alleging design-defect claims helped drive Wyeth Laboratories from the market in 1984. Congress was not willing to tolerate the risk that such events would recur, concluding that the "withdrawal of even a single [additional] manufacturer would present the very real possibility of vaccine shortages." 1986 House Report at 7.

The vaccine market today is subject to disruption just as it was in 1986, as there are still only one or two manufacturers for a majority of the vaccines listed on the routine childhood immunization schedule. See Food & Drug Administration, *Complete List of Vaccines Licensed for Immunization and Distribution in the US*, http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm (last modified June 3, 2010). If Section 22(b)(1) is interpreted to allow the assertion of design-defect claims, the threat to the vaccine supply from civil litigation would be at least as severe as in 1986. It is easy to *allege* that a vaccine causes a particular affliction (because nearly every child receives vaccines in the first six months of life, before most neurodevelopmental disorders first manifest) and

that some alternative vaccine design supposedly could have been employed.

For example, since 2001, over 350 civil actions (most involving design-defect claims) have been filed against vaccine manufacturers that allege that childhood vaccines caused the recipient to develop autism. Evans at S134. Another 5,000 petitions alleging neurological injury from childhood vaccines are currently pending in the "Omnibus Autism Proceeding" in Vaccine Court. See *National Vaccine Injury Compensation Program Statistics Report, supra*. Petitioners in these cases have the burden to prove causation because their claimed injuries are not on the Vaccine Injury Table—a circumstance that reflects the broad and deep scientific consensus outside of litigation that childhood vaccines do not cause autism.[29] Two different causation theories were presented in six test cases drawn from the omnibus proceeding, and, after full evidentiary hearings, Special Masters rejected both theories, in all six test cases, as scientifically unsupportable.[30] Were this Court to hold that the

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[29] *See* FDA, *Thimerosal in Vaccines*, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm (last modified March 31, 2010); CDC, *Frequently Asked Questions About Thimerosal (Ethylmercury)*, http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/thimerosal_faqs.html#6 (last modified Feb. 17, 2010); Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* 7 (2004).

[30] Regarding the first theory (that Measles Mumps Rubella vaccine combined with other vaccines that contain the preservative thimerosal supposedly causes autism), see *Hazlehurst* v. *Sec'y of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), sustained, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Cedillo* v. *Sec'y of HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), sustained, 89 Fed. Cl. 158

Vaccine Act does not preempt design-defect claims, claimants in the omnibus proceeding could be emboldened to pursue a flood of civil actions.

As the American Academy of Pediatrics has explained, the consequences of such litigation for the vaccine supply (and ultimately for public health) could be devastating. See Brief *Amici Curiae* Of The American Academy Of Pediatrics *et al.* In Support Of Petitioners, *Am. Home Prods. Corp.* v. *Ferrari*, No. 08-1120 (Apr. 8, 2009), at 7. Thus, the purpose and policy of the Vaccine Act, like its text, structure and legislative history, support an interpretation of Section 22(b)(1) that precludes state-law design-defect claims categorically.

(2009), appeal docketed, No. 10-5004 (Fed. Cir. argued June 10, 2010); *Snyder* v. *Sec'y of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), sustained, 88 Fed. Cl. 706 (2009).

Regarding the second theory (that thimerosal by itself causes autism), see *Dwyer* v. *Sec'y of HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Mar. 12, 2010); *King* v. *Sec'y of HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Mar. 12, 2010); *Mead* v. *Sec'y of HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Mar. 12, 2010).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

DANIEL J. THOMASCH
RICHARD W. MARK
E. JOSHUA ROSENKRANZ
LAUREN J. ELLIOT
JOHN L. EWALD
ORRICK, HERRINGTON & SUTCLIFFE LLP
51 W. 52nd Street
New York, NY 10019
(212) 506-5000

KATHLEEN M. SULLIVAN
Counsel of Record
FAITH E. GAY
SANFORD I. WEISBURST
WILLIAM B. ADAMS
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Ave., 22nd Flr.
New York, NY 10010
(212) 849-7000
kathleensullivan@quinnemanuel.com

Counsel for Respondent

July 23, 2010

REPLY BRIEF

No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD, AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

REPLY BRIEF FOR PETITIONERS

JOHN EDDIE WILLIAMS
JOHN T. BOUNDAS
WILLIAMS KHERKHER HART BOUNDAS, LLP
8441 Gulf Freeway
Suite 600
Houston, Texas 77017-5051
(713) 230-2200

COLLYN A. PEDDIE
THE LAW OFFICES OF COLLYN PEDDIE
440 Louisiana, Suite 1710
Houston, Texas 77002-1689
(713) 422-1205

DAVID C. FREDERICK
Counsel of Record
DEREK T. HO
BRENDAN J. CRIMMINS
JANIE N. KUCERA
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

August 23, 2010

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Section 22(b)(1)'s language, structure, and purposes evidence Congress's intent to incorporate the well-recognized standards of comment k to Restatement (Second) of Torts § 402A (1965). Under that rule, a manufacturer is not liable for injuries caused by a vaccine if it can demonstrate that any safety risks were "unavoidable," the vaccine was manufactured properly, and the warning label was adequate. That rule advances the critical policy of incentivizing manufacturers to deploy the latest scientific advances to improve patient safety.

Wyeth's contention that § 22(b)(1) confers blanket immunity from liability for defective design disregards the established meaning of the term "unavoidable" and renders a large portion of § 22(b)(1) surplusage. It also implausibly assumes that Congress displaced longstanding tort remedies recognized in every state and granted immunity for all design defects—even those that are willful or reckless—without saying so in plain language. Congress did not sweep so broadly. Instead, Congress enacted a compromise that conferred major benefits on manufacturers without precluding all design-defect claims. Congress expanded comment k's exemption for unavoidably unsafe designs to include fault-based claims, in addition to strict-liability. But Congress retained comment k's methodology that such exemption applies only if the vaccine is shown on a case-by-case basis to be unavoidably unsafe.

Wyeth's interpretation also reaches an untenable policy result. Under Wyeth's reading, all FDA-approved vaccines are forever deemed "unavoidably unsafe," even though federal regulations do not require manufacturers to upgrade vaccines based on scientific advances. Wyeth claims it had no obli-

gation to improve a DTP vaccine designed using 1940s-era scientific knowledge, even though it knew in the 1960s the design was outmoded; sold the vaccine for another three decades based on a cost-benefit analysis that put corporate profits ahead of patient safety; and eventually withdrew the vaccine from the market in the 1990s. This Court should reject Wyeth's contention as inconsistent with normal modes of statutory interpretation, antithetical to the traditional role of courts to administer justice in individual cases, and anathema to sound public policy.

ARGUMENT

I. SECTION 22(b)(1) PRESERVES LIABILITY FOR INJURIES CAUSED BY AVOIDABLE SIDE EFFECTS

Section 22(b)(1) provides that vaccine manufacturers are exempt from liability "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). Under that provision's plain language, Wyeth must meet three requirements for the liability exemption in § 22(b)(1) to apply. The injury must have resulted from side effects that were "unavoidable" as that term was understood when Congress enacted the NCVIA—i.e., not preventable through use of a safer alternative design. In addition, the injury must have "resulted . . . even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The Act's structure reinforces that conclusion, and the presumption against preemption resolves any remaining doubt in favor of preserving design-defect claims. *See* Pet. Br. 28-41.

The contrary arguments of Wyeth and its *amici* are unpersuasive.

A. Wyeth's Textual Arguments Lack Merit

1. Wyeth contends (at 30) that the clause "even though the vaccine was properly prepared and was accompanied by proper directions and warnings" "immediately modifie[s]" the term "unavoidable," such that proper preparation and proper directions and warnings are the only conditions that must be met to establish that a side effect is "unavoidable." *See also* U.S. Br. 10. That textual construction is unpersuasive.

First, Wyeth's interpretation contradicts the established meaning of "unavoidable." *See* Pet. Br. 28-31. Comment k and the cases applying it use "unavoidable" to refer to inherent safety risks in a product that is "*incapable* of being made safe for [its] intended and ordinary use." Restatement § 402A cmt. k (emphasis added); *see* Pet. Br. 30-31 (citing cases). Manufacturing and labeling defects, by contrast, are always *avoidable*. Proper manufacturing and proper warnings are additional requirements to avoid strict liability under comment k, but they are not elements of "unavoidability," which relates to the product's *design*. Wyeth's construction turns comment k upside-down, by reading "unavoidable" to depend solely on two conditions that manufacturers are always capable of controlling and by eliminating comment k's traditional "unavoidability" inquiry into whether the product was "*incapable* of being made safe." Wyeth's interpretation thus violates the canon that Congress intends terms of art to have their established legal meaning. *See* Pet. Br. 31.

Second, Wyeth's interpretation ignores the similarity between the language and structure of § 22(b)(1)

and comment k, which Congress expressly used as a guide. Comment k provides:

> *k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for the unfortunate consequences attending their use . . . .

Restatement § 402A cmt. k.

As Dean Prosser wrote it, comment k is focused on products that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.* "[S]uch products"—i.e., products that are "incapable of being made safe"—are "[u]navoidably unsafe." *Id.* Sellers of unavoidably unsafe products are exempt from strict liability, "*with the qualification that* they are properly prepared and marketed, and proper warning is given." *Id.* (emphasis added). Section 22(b)(1) follows the same structure: Vaccine manufacturers are exempt from liability if the injuries resulted (1) "from side effects that were unavoidable"—i.e., "incapable of being made safe" "in the present state of human knowledge"—and (2) "even though" the vaccine "was properly prepared and was accompanied by proper

directions are warnings." 42 U.S.C. § 300aa-22(b)(1).[1] Interpreting proper manufacturing and proper warning as supplemental requirements also comports with the use of "even though" as a subordinate conjunction. *See* Bryan A. Garner, *The Elements of Legal Style* 64-65 (1991) (explaining that, for clarity, subordinate conjunctions place "lesser ideas"—here, proper warning and manufacture—in subordinate clauses with "greater" ideas—unavoidability—in "main clauses").

Third, had Congress wanted to eliminate design-defect liability, it could have exempted manufacturers from liability "if . . . the vaccine was properly prepared and was accompanied by proper directions and warnings." Wyeth functionally excises the 13 omitted words—"the injury or death resulted from side effects that were unavoidable even though."[2] The point is not simply that Congress could have been more linguistically efficient (*see* U.S. Br. 12): Wyeth's interpretation violates settled canons of construction by rendering void the key statutory term—"unavoidable." *See Duncan v. Walker*, 533 U.S. 167, 174 (2001) (Court is "especially unwilling" to treat statutory terms as surplusage "when the term occupies so pivotal a place in the statutory scheme"). Petitioners' correct interpretation gives effect to all of § 22(b)(1), by retaining comment k's requirement of

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[1] Wyeth (at 32) and the government (at 12) incorrectly assert that petitioners' interpretation disregards the clause following "unavoidable." That clause embodies comment k's "qualification" that, to be exempt from strict liability, the seller of an unavoidably unsafe product must ensure proper preparation and proper warning.

[2] Petitioners' opening brief (at 40) contained a printing error in not italicizing the final two omitted words, "even though."

unavoidability and its additional requirements of proper preparation and warnings.

Fourth, Wyeth's reading of § 22(b)(1) renders largely superfluous § 23(d)(2), which establishes a regulatory-compliance defense to liability for punitive damages. *See TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (rejecting interpretation that would render statutory language "insignificant, if not wholly superfluous") (internal quotations omitted); Pet. Br. 36. Under Wyeth's view (at 31), § 22(b)(1) already bars *all* liability except where a manufacturer could not show regulatory compliance because it failed to "adhere to the vaccine's FDA-approved specifications, or . . . did not comply with regulatory requirements or withheld information from FDA."

2. Wyeth (at 41-42) quibbles with petitioners' statement that Congress's use of "unavoidable" reflected its intent to "codify" comment k in § 22(b)(1). Instead, it asserts that Congress merely "looked to 'the principle of Comment k'" in determining that *all* vaccine side effects from design defects are unavoidable as a matter of law. But that categorical approach is directly contrary to comment k's "principle," as shown by the comment's language and the decisions applying it.

First, comment k's text, which Wyeth largely ignores, makes clear that unavoidability is an issue for judges and juries to resolve in each case. Comment k refers to the unavoidable risks of "*some*"—not all—"products" and "*many*"—not all—"vaccines." Restatement § 402A cmt. k (emphases added). That language cannot be reconciled with the categorical approach Wyeth espouses.

Second, a majority of states in 1986 required manufacturers to make a case-specific showing that

a product was "unavoidably unsafe" to qualify for comment k's exemption from strict liability.[3] Wyeth cites (at 43 n.25) the minority of cases holding that all prescription-drug or vaccine side effects are unavoidable. But Wyeth offers no evidence that Congress adopted the *minority* position in § 22(b)(1). *Cf. Field v. Mans*, 516 U.S. 59, 70 n.9 (1995) (the Court construes statutes "to incorporate the general common law" and "the dominant consensus of common-law jurisdictions, rather than the law of any particular State").

Wyeth asserts (at 41-42) that certain differences between comment k and § 22(b)(1)—most notably, that comment k set forth an exemption only from strict liability, whereas § 22(b)(1) is not so limited—preclude reliance on decisions applying comment k in interpreting § 22(b)(1). But the fact that Congress may have altered the *scope* of manufacturers' exemption does not logically imply that it changed comment k's case-specific standard for determining their *eligibility* for exemption. To the contrary, Congress's codification of the term "unavoidable" reflects

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[3] *See* Pet. Br. 34 n.17 (citing cases showing seven states took case-specific approach). Courts applying the laws of four other states similarly had adopted that approach. *See Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1322-24 (Kan. 1986); *Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290-91 (7th Cir. 1972) (Indiana law); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 128 (9th Cir. 1968) (Montana law); *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1146 (Fla. Dist. Ct. App. 1981) (adopting a "balancing approach" to whether a product is unavoidably unsafe). The Oregon case Wyeth cites (at 43 n.25) predated Oregon's 1979 statute enacting comment k. *See* Or. Rev. Stat. § 30.920(3). By 1986, Oregon had adopted the majority case-by-case approach. *See Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1337 (9th Cir. 1985).

its intent to codify the term's well-known, case-specific understanding.

3. Wyeth (at 34) and the government (at 15) also criticize petitioners' reading of § 22(b)(1)'s text on the ground that it would weaken manufacturers' liability protections and deprive them of any benefit from the NCVIA. Neither is true.

First, § 22(b)(1) created certainty for manufacturers by establishing a uniform national liability rule against the backdrop of unsettled state law. Before 1986, at least one state had rejected comment k. *See Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 52 (Wis. 1984) ("We conclude that the rule embodied in comment k is too restrictive and, therefore, not commensurate with strict products liability law in Wisconsin. Drug companies, like other sellers or manufacturers, have a duty to produce and market reasonably safe products."). Further, many states had not addressed the applicability of comment k to vaccines and could have followed Wisconsin's refusal to adopt comment k. Section 22(b)(1) thus represented an enormous benefit for manufacturers, removing the risk in those states of being held strictly liable for even unavoidable side effects.

Second, in contrast to comment k, which exempted manufacturers only from claims of strict products liability, § 22(b)(1) created a brand-new defense to fault-based liability. The NCVIA thus changed the law "in most states" under which the plaintiff could "proceed under a negligence cause of action even if comment k provide[d] a defense to strict liability." *Toner v. Lederle Labs.*, 828 F.2d 510, 512 (9th Cir. 1987) (Kennedy, J.).

Section 22(b)(1)'s unprecedented exemption from *all* civil liability also answers Wyeth's (at 44) and

the government's (at 17-18) erroneous contentions that petitioners' reading of § 22(b)(1) would make manufacturers worse off in the minority states that followed the categorical approach to comment k. Even assuming § 22(e) would displace a categorical state rule,[4] § 22(b)(1) still provides important additional protections from fault-based liability that did not exist even in states adopting a categorical approach to comment k for strict-liability claims. *See Toner*, 828 F.2d at 512 (holding under Idaho law that a finding of unavoidability provides no defense to negligent design-defect liability).

Third, the NCVIA imposed substantial limitations on failure-to-warn and punitive-damages claims that did not exist under state law. It adopted a presumption of proper directions and warnings for purposes of § 22(b)(1) when the manufacturer obeys federal requirements and codified the learned intermediary doctrine. *See* 42 U.S.C. § 300aa-22(b)(2), (c). It also established a regulatory-compliance defense to punitive damages. *See id.* § 300aa-23(d)(2).

Fourth, the NCVIA barred civil actions by any claimant who has not sought compensation (and rejected any award received) in the Vaccine Court. *See id.* §§ 300aa-11(a)(2)(A), 300aa-21(a). It thus "discourages" litigation "by providing fairly generous,

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[4] Contrary to Wyeth's and the government's assumptions, it is not clear that § 22(e) preempts any state statute establishing categorical comment-k protection for all FDA-approved vaccines. Section 22(e) only prevents states from "barr[ing]" "civil action[s]" permitted by the NCVIA—for example, by creating their own mandatory compensation regimes. *See* H.R. Rep. No. 99-908, pt. 1, at 27 (1986) ("1986 Report"); Pet. Br. 42-43. A liability rule does not "bar" any action. *Cf. Evans v. Lederle Labs.*, 167 F.3d 1106, 1110-11 (7th Cir. 1999) (holding that § 22(e) does not preempt state statutes of limitations).

more easily obtainable, Vaccine Court awards." *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 4-5 (1st Cir. 1994) (Breyer, C.J.). Moreover, Vaccine Court awards are paid with the proceeds of an excise tax levied on vaccines—not out of vaccine manufacturers' corporate coffers—thus functionally creating a valuable insurance policy for vaccine-related injuries. *See* 42 U.S.C. § 300aa-15(i)(2); 26 U.S.C. §§ 4131-4132, 9510.

4. Wyeth (at 31), but not the government, asserts that, by referring to "*the* vaccine" in § 22(b)(1), Congress barred courts from imposing liability if the manufacturer could have avoided the harmful side effect by using a safer alternative design. But Wyeth concedes that § 22(b)(1) permits claims for manufacturing defects and failure to warn. Those claims, too, require courts to consider whether the manufacturer should have sold a different vaccine—namely, one manufactured better or bearing better warnings. Thus, Congress's choice of the definite article does not bar courts from considering whether the manufacturer should have sold a vaccine different from the one actually administered.

Further, Wyeth's argument depends on an erroneous premise. Wyeth asserts (at 31, 37-39) that a vaccine's "labeling" is within the manufacturer's "exclusive control," whereas "manufacturers are absolutely barred from changing the design of an approved vaccine" prior to FDA approval. That mischaracterizes FDA's regulations. Under those regulations, "[b]efore distributing a product made using a change [in the product]," the manufacturer bears responsibility for "assess[ing] the effects of the change and demonstrat[ing]" through appropriate means "the lack of adverse effect of the change" on

the vaccine's safety and effectiveness. 21 C.F.R. § 601.12(a)(2). The manufacturer also must inform FDA about "each change in the product." *Id.* § 601.12(a)(1). "[M]ajor changes" with "a substantial potential to have an adverse effect" on safety or efficacy require FDA approval before the manufacturer may implement them, *id.* § 601.12(b), whereas the manufacturer can implement changes "in the product" with only a "moderate" or "minimal" "potential to have an adverse effect" without preapproval, *id.* § 601.12(c)(1), (d)(1). Design changes that *improve* vaccine safety do not require preapproval. The government offers no authority for its contrary assertion (at 20-21). Indeed, § 601.12(b)(2)(i) specifically contemplates that "changes in the qualitative or quantitative formulation" of a vaccine having only a "moderate" or "minimal" "potential to have an adverse effect" on safety or efficacy may be implemented without prior approval.[5]

Wyeth's related suggestion that, as to vaccine design, it is merely a passive participant in "the federal regulatory process" (Br. 31-32) betrays the same "fundamental misunderstanding" about the federal regulatory scheme this Court corrected in *Wyeth v. Levine*, 129 S. Ct. 1187, 1197 (2009). As the Court there explained, a "central premise" of FDA regulation is that the manufacturer "bears responsibility" for its product. *Id.* at 1197-98. As with labeling,

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[5] Wyeth asserts (at 31), without citation, that vaccine design changes always entail "extensive clinical trials." Under FDA regulations, however, even "major changes" in a vaccine's "formulation" do not necessarily require clinical trials. *See* 21 C.F.R. § 601.12(a)(2) (permitting manufacturers to "assess the effects of [a] change . . . through *appropriate validation* and/or other clinical and/*or nonclinical* laboratory studies") (emphases added).

see 21 C.F.R. § 601.12(f), a vaccine manufacturer remains obligated to identify and evaluate proposed design changes, and FDA's role is reactive—to confirm the changes do not adversely affect the vaccine's safety or effectiveness. That regulatory regime reflects the common-sense reality that the manufacturer, not FDA, is best-positioned to know how to design, manufacture, and describe its product. Critically, Wyeth identifies nothing authorizing FDA to require a manufacturer to adopt a safer alternative design for an approved vaccine. *See* Wyeth Br. 11-14; *see also* Pet. Br. 9 (noting absence of such a provision).

5. Finally, Wyeth (at 45) and the government (at 18) argue that the presumption against preemption should not apply in this case because § 22(e) would preempt state laws eliminating design-defect claims if petitioners' reading of § 22(b)(1) were adopted. It is far from clear that § 22(e) has that effect. *See supra* note 4. In all events, this Court has recognized that the presumption has particular force when preemption would abolish "state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). The presumption thus supports petitioners' reading of § 22(b)(1), which preserves traditional defective-products liability claims.

B. The NCVIA's Structure Supports Preserving Design-Defect Claims

Wyeth's arguments regarding the NCVIA's structure (at 36-40) are principally unpersuasive policy arguments masquerading as statutory construction. Wyeth suggests that the Act fulfills tort law's two primary functions—encouraging manufacturers to exercise due care and compensating injured victims—and thus renders design-defect liability unneces-

sary and counterproductive. The Act, however, was not intended to, and does not, supplant tort law's traditional roles.

1. Wyeth first contends (at 37) that "administrative regulation" ensures "the best vaccine design." But Wyeth can identify no statutory or regulatory requirement that manufacturers continue to improve vaccine designs to eliminate avoidable side effects. Wyeth highlights (at 36) Congress's general instruction to *the Secretary of Health and Human Services* ("HHS") to promote the development of safer vaccines. *See* 42 U.S.C. § 300aa-27(a). But that direction imposes no enforceable mandate on, and creates no incentives for, *manufacturers*. Wyeth also invokes (at 37) precatory language announcing Congress's intention that the National Vaccine Program "achieve optimal prevention against adverse reactions to vaccines," 42 U.S.C. § 300aa-1, but that likewise does nothing to alter manufacturer behavior.

Because nothing in the federal regulatory regime obligates manufacturers to adopt safer vaccine designs, Wyeth's hackneyed claim (at 36-37) that this case presents a choice between "expert federal agencies" and "lay juries" is misplaced. In fact, for design claims, the choice is between state law and no regulation. If Wyeth prevails, vaccine manufacturers will have no legal duty to improve the design of their vaccines to account for scientific advances and instead will be free to continue marketing more dangerous vaccines that earn greater profits.[6]

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[6] Wyeth asserts (at 38) that liability for defective design risks "produc[ing] varying decisions in different States about whether any given vaccine design is defective." But § 22(b)(1) avoids that result by creating a *federal* standard exempting manufacturers from liability for "unavoidable" side effects.

Wyeth also contends (at 37-39) that § 22(b) provides incentives for manufacturers to produce safer vaccines by permitting liability for improper manufacturing and failure to warn subject to a regulatory-compliance defense. But encouraging vaccine makers to manufacture their products properly and to comply with applicable statutory and regulatory labeling provisions provides no incentive to improve vaccine designs. Further, the folly of Wyeth's description of the regulatory requirements for disclosure of information and reporting of adverse events (at 37-39) lies in the inherent limitations of those duties: neither Wyeth nor the government disputes that FDA receives *no* reports about safer alternative designs. *See* Pet. Br. 9.

Wyeth also suggests (at 39) that this case is different from *Levine* because the manufacturer there could have changed the labeling pending FDA approval. As the *Levine* Court recognized, however, "FDA retains authority to reject labeling changes made pursuant to the [changes-being-effected] regulation." 129 S. Ct. at 1198. Thus, in both cases, FDA ultimately must approve any change in labeling or design, and in both situations the proposed change originates with the *manufacturer*, not FDA. Moreover, as with prescription drugs, FDA permits changes to vaccines before agency approval if they do not have a "substantial potential to have an adverse effect" on safety or efficacy. 21 C.F.R. § 601.12(c)(1), (d)(1). Thus, as in *Levine*, vaccine manufacturers can *improve* the safety and efficacy of their designs without prior FDA approval.

2. Wyeth also contends (at 39-40) that the NCVIA's administrative compensation scheme performs the compensatory function of civil actions. But

it ignores the Compensation Program's real and substantial limitations—including the severe restrictions on discovery, the omissions in the Vaccine Injury Table, and the difficulties of proving causation for non-Table injuries. *See* Willner *Amicus* Br. 20-31 (describing Program's operation).

More fundamentally, Wyeth's contention conflicts with the NCVIA's structure. Congress created an administrative compensation process (§§ 10-19), authorized injured patients to file civil actions after pursuing claims through that process (§ 21), and provided a limited exemption from liability for injuries resulting from unavoidable side effects (§ 22(b)(1)). Considering that Congress plainly intended for civil actions to continue notwithstanding the creation of the Compensation Program, the Program's existence alone cannot justify transforming § 22(b)(1)'s liability exemption into an immunity for all design-defect claims.

II. THE NCVIA'S LEGISLATIVE HISTORY DEMONSTRATES CONGRESS'S INTENT TO PRESERVE DESIGN-DEFECT LIABILITY

Contrary to Wyeth's unpersuasive reading of a few snippets from the 1986 House Report, the legislative record contains clear indicia that Congress intended to preserve, rather than eliminate, design-defect liability (*see* Pet. Br. 44-51).

A. The 1986 Report Supports Petitioners' Interpretation Of § 22(b)(1)

Wyeth misreads both passages from the 1986 Report on which it relies. First, the 1986 Report's statement that the Committee "intends that the principle in Comment K regarding 'unavoidably unsafe' products, i.e., those products which in the

present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that *such products* not be the subject of liability in the tort system" supports petitioners' position. 1986 Report at 26 (emphasis added). The phrase "such products" comes directly from comment k and refers to "those products which in the present state of human skill and knowledge cannot be made safe." *See id.*; *accord* Restatement § 402A cmt. k. That language confirms that Congress intended "unavoidable" in § 22(b)(1) to incorporate comment k's core principle that a particular product is exempt from liability only if it cannot be *designed* more safely. Contrary to Wyeth's suggestion, "such products" does not refer categorically to all "vaccines covered in the bill," because, even under Wyeth's interpretation of § 22, covered vaccines *are* "the subject of liability in the tort system" if they are improperly manufactured or labeled.

Wyeth's misunderstanding of "such products" also leads it to misinterpret the Committee's ensuing statement: "Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should [sic] pursue recompense in the compensation system, not the tort system." 1986 Report at 26. The omission of defective design from that passage does not indicate an intent to eliminate liability for unsafe vaccines, because the 1986 Report already had made clear in the preceding paragraphs that it was adopting comment k and exempting from design-defect liability only "those products" that are unavoidably unsafe. Congress's

reference to the NCVIA's Compensation Program as an "*appealing alternative* to the tort system" also confirms that it was meant to be a carrot, not a stick. *Id.* (emphasis added); *see also id.* at 12-13 (stating that the "speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation").

The full legislative record presaging passage of the NCVIA confirms petitioners' reading. *See, e.g., Board of Governors v. First Lincolnwood Corp.*, 439 U.S. 234, 245 n.11 (1978) (consulting floor statements to resolve ambiguity in House report). First, the Committee rejected an amendment that would have expressly eliminated design-defect liability for failure to develop a safer vaccine. *See* Pet. Br. 45. Wyeth asserts that the mark-up session is not authoritative, but the Committee's rejection of a proposal embodying the very liability rule Wyeth now advocates evidences the "collective understanding of those Congressmen involved in drafting" the NCVIA that liability for avoidable injuries should be preserved. *Garcia v. United States*, 469 U.S. 70, 76 (1984) (internal quotations omitted). The floor speeches by the Act's proponents and statements by industry leaders further corroborate Congress's intent to preserve design-defect liability. *See Atherton v. FDIC*, 519 U.S. 213, 228-30 (1997) (relying on floor statements and Senate report).[7] Tellingly, Wyeth

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[7] Wyeth's efforts to explain away those statements are unpersuasive. The bill on which Lederle's President, Robert Johnson, commented, H.R. 5184, 99th Cong. (1986), was more manufacturer-friendly than the final legislation because it contained, in addition to § 22(b)(1), a separate provision precluding

cannot cite a single statement in the 1986 debates supporting its interpretation of § 22(b)(1).

B. The 1987 Report Is Authoritative And Confirms Petitioners' Interpretation Of § 22(b)(1)

The 1987 Report unequivocally answers the question presented: "[T]here should be *no misunderstanding* that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. The question is left to the courts to determine in accordance with applicable law." H.R. Rep. No. 100-391, pt. 1, at 691 (1987) ("1987 Report"). Wyeth dismisses that as unreliable "post-enactment legislative history" (at 49). But the 100th Congress's intent is, if anything, *more* relevant to the proper interpretation of § 22(b)(1) than that of the 99th Congress, because the later Congress enacted the funding legislation necessary to give the 1986 law, including § 22(b)(1), any legal effect. Without the 1987 bill, § 22(b)(1) was a nullity. Consequently, the 1987 Report should control because the 100th Congress, in substance, "enacted" § 22(b)(1) into law. *See Oscar Mayer & Co. v. Evans*, 441 U.S. 750, 758 (1979) ("It is the intent of the Congress that enacted [the section] . . . that controls.") (internal quotations omitted, alterations in original).

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a plaintiff from bringing a civil action for damages "on a theory of strict liability, absolute liability, or any other theory in which the wrongful conduct of the defendant is not the basis of liability." *Id.* § 2122(c)(1). Mr. Johnson's observation that H.R. 5184 left "open to litigation" claims asserting defective design applies *a fortiori* to the NCVIA. *See* Pet. Br. 44-45. Wyeth does not dispute that other vaccine company officials' statements support petitioners' position.

It is inconsequential that the 100th Congress "did not modify" § 22(b)(1). Wyeth Br. 50. Members of Congress voted for the 1987 law, and the President signed it, after extensive further debate about the provisions of the 1986 bill, including specifically § 22(b)(1). *See* Pet. Br. 48-50. Statements by all participants in that debate—including members of Congress, the Reagan Administration, and industry officials—confirm that vaccine manufacturers were not exempt from design-defect liability for injuries due to avoidable side effects.[8] The understanding of the 100th Congress, as the lawmakers who put § 22(b)(1) into effect, is authoritative. *See District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008).

III. IMMUNIZING VACCINE MANUFACTURERS FROM LIABILITY FOR FAILING TO MAKE THEIR PRODUCTS AS SAFE AS REASONABLY POSSIBLE DOES NOT PROMOTE THE NCVIA'S PURPOSES

No sound policy rationale supports exempting vaccine manufacturers from civil liability when they design vaccines that are more dangerous than necessary. Holding manufacturers accountable in these circumstances will not cause them to stop supplying vaccines, because they reap enormous profits and face little competition in that lucrative market.

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[8] Wyeth baselessly disparages the 1987 Report as representing a "strategic manipulation[] of legislative history" "to amend a statute through a committee report." Wyeth Br. 50 (internal quotations omitted). The Energy and Commerce Committee's composition barely changed between the 99th and 100th Congress. The same chairman, Rep. Waxman, oversaw both the 1986 and 1987 Reports, and his floor statements in both Congresses confirm that § 22(b)(1) was not intended to eliminate design-defect claims.

A. Immunizing Vaccine Manufacturers From Civil Liability For Avoidable Side Effects Will Jeopardize Public Health

This Court has long recognized that an "important purpose of defective-product tort law is to encourage the manufacture of safer products." *Saratoga Fishing Co. v. J.M. Martinac & Co.*, 520 U.S. 875, 881 (1997); *see Levine*, 129 S. Ct. at 1202-03; *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 450-51 (2005); *Schafer*, 20 F.3d at 3; *Toner*, 828 F.2d at 513. Civil liability for avoidable design flaws promotes public health by incentivizing manufacturers to "forestall [civil] actions through product improvement." *Bates*, 544 U.S. at 451 (internal quotations omitted). It also encourages childhood vaccination by promoting public confidence that children will not be harmed by outmoded designs such as the 1940s-era whole-cell pertussis vaccine at issue here.

Wyeth nonetheless argues (at 54) that design-defect claims should be eliminated because the NCVIA provides "comprehensive" "incentives to develop safe and efficacious vaccines without such tort liability." As discussed above (*supra* p. 13), the Act generally charges HHS with promoting safer vaccines, but it creates no obligation or incentives for manufacturers to design, seek approval for, or market safer vaccines. Nor does the fact that pharmaceutical companies have brought vaccines to market since 1986 show that tort liability is unnecessary to promote product safety: Manufacturers have tremendous profit motive to bring *new* vaccines to market,[9] and new vaccines (*e.g.*, cancer, HIV/AIDS)

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[9] *See* Gloria Lau, *Wyeth Looks Toward Future While Past Still Haunts*, Investor's Bus. Daily, Nov. 28, 2005, at A8 (quoting Wyeth's CFO, Ken Martin, as reporting "an 85% to 90%

also are the focus of the government research funding the government touts (at 22). But the admitted lack of robust competition, with only one or two manufacturers for most vaccines (*see* Wyeth Br. 55), creates little market incentive for manufacturers to replace established but outmoded designs with safer alternatives. *See* 2 Earl W. Kintner, *Federal Antitrust Law* § 11.3, at 306 (1980); Michael Mussa & Sherwin Rosen, *Monopoly and Product Quality*, 18 J. Econ. Theory 301, 301 (1978) ("[T]he monopolist almost always reduces the quality sold to any customer compared with what would be purchased under competition.").

This case demonstrates the important incentives civil liability creates. Government studies show that the DTaP vaccine is "much safer than" DTP. CDC, Diphtheria, Tetanus, and Acellular Pertussis (DTaP) Vaccine, *available at* http://www.cdc.gov/vaccinesafety/Vaccines/dtap/dtapindex.html. Lederle was aware of that as early as the 1960s, but, according to its own internal documents, deliberately stopped research on an acellular alternative because the economic gains did not justify the costs. *See* Pet. Br. 18. Neither federal regulation nor market incentives sufficiently motivated Lederle to invest in product improvement, and the whole-cell DTP vaccine continued to be administered to children for decades longer. Under Wyeth's untenable interpretation of § 22(b)(1), the whole-cell vaccine that Wyeth withdrew from the market would be considered unavoidably unsafe today if properly manufactured and labeled.

It is no answer that design changes require significant research and FDA approval. *See* Wyeth Br. 20-

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gross profit margin" on the vaccine Prevnar, with substantially lower marketing costs compared to other drugs).

21; U.S. Br. 32. Lederle's knowing abandonment of promising research delayed the very testing and study that could have led to the acellular alternative being approved and marketed long before 1996. Wyeth's extreme position would immunize manufacturers even where they *knowingly* or *intentionally* sacrifice children's safety in the name of profit. No sound public policy supports that result.[10]

B. Wyeth's Assertion That Civil Liability For Injuries Caused By Outmoded Designs Will Cause Vaccine Shortages Is Unfounded

Obligating manufacturers to make safer vaccines will not lead to a rash of meritless lawsuits, force them to exit the market, or destabilize the vaccine supply. Nearly 25 years of experience disproves Wyeth's prediction (at 55) that claimants denied recovery in the Vaccine Court will "forg[e] ahead" with meritless court claims. "Virtually all . . . petitioners, *even those who were not awarded compensation under the [Compensation Program],*" have chosen to accept that court's determination. Stanley A. Plotkin et al., *Vaccines* 1673 (5th ed. 2008) (emphasis added); *see also Schafer*, 20 F.3d at 5 ("[A] petitioner to whom the Vaccine Court gives nothing may see no point in trying to overcome tort law's yet more serious

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[10] The government contends (at 21, 25) that liability is unwarranted because vaccines have "such a low rate of unavoidable serious side effects . . . that they may not be discovered even in massive clinical trials." But side effects unknowable to the manufacturer are considered "unavoidable" under comment k. *See* Restatement § 402A cmt. k (product is unavoidably unsafe if it has "*known* but apparently reasonable risk") (emphasis added); *Ortho Pharm. Corp. v. Heath*, 722 P.2d 410, 415 (Colo. 1986) ("the risk must be a *known* one") (emphasis added), *overruled on other grounds, Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992).

obstacles to recovery."); U.S. Br. 26-28. Moreover, decades of adjudicating claims against prescription-drug manufacturers for avoidable injuries in states that apply comment k on a case-specific basis have not discouraged the marketing of prescription drugs.

Wyeth also offers no reason why judges cannot dispose of meritless claims that do find their way into court. Judges routinely grant summary judgment if, as Wyeth asserts is true of the autism cases, there is no evidence of product defect or causation.[11] The presumption against preemption, which reflects respect for federalism, means little if this Court accepts Wyeth's invitation to *assume* that courts are incapable of adjudicating state-law claims responsibly and in accordance with law.

Wyeth also warns that the vaccine market is as precarious today as it was in 1986. On Wall Street, however, manufacturers are touting the "golden age of vaccines." Robert Langreth, *Booster Shot*, Forbes, Nov. 12, 2007, at 78, 80 (noting Lehman Brothers' prediction that "[t]he $13 billion global vaccine business will grow 18% a year to $30 billion in 2011," "well above the 4.4% annual growth expected for the drug industry overall"). The limited number of manufacturers highlights the high profit margins of entrenched manufacturers whose competitors face daunting barriers to entry. *See* FD Wire, *Wyeth at Bear, Stearns & Co. Healthcare Conference—Final* (Sept. 10, 2007) (statement by head of Wyeth's vaccine unit that vaccines have "very strong business characteristics," "[i]ncluding long product life cycles

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[11] *See, e.g., Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760 (Tex. App. 2009); *Viramontes v. Pfizer, Inc.*, No. C054574, 2008 WL 2477443 (Cal. Ct. App. June 20, 2008); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915 (Kan. 1990).

and high barriers to entry" and "significant growth potential"). Wyeth itself views the "ongoing strength of [its] . . . vaccine franchises" as a main driver of its overall revenue growth. Wyeth, News Release (July 23, 2009), *at* http://www.wyeth.com/irj/servlet/prt/portal/prtroot/com.sap.km.cm.docs/wyeth_xml/home/news/announcements/1248346908863.pdf.[12] Wyeth's alarmist warnings of imminent market exit are simply implausible given the lucrative profits it earns from vaccines and the significant protections it enjoys under the NCVIA.

CONCLUSION

The judgment of the court of appeals should be reversed.

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[12] On October 15, 2009, Pfizer acquired Wyeth for $68 billion, in significant part because of Wyeth's vaccine business. *See* Press Release, *Pfizer To Acquire Wyeth* (Jan. 26, 2009), *at* http://media.pfizer.com/files/investors/presentations/Acquisition_Press_Release_012609.pdf.

Respectfully submitted,

JOHN EDDIE WILLIAMS
JOHN T. BOUNDAS
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway
Suite 600
Houston, Texas 77017-5051
(713) 230-2200

COLLYN A. PEDDIE
THE LAW OFFICES OF
COLLYN PEDDIE
440 Louisiana, Suite 1710
Houston, Texas 77002-1689
(713) 422-1205

DAVID C. FREDERICK
Counsel of Record
DEREK T. HO
BRENDAN J. CRIMMINS
JANIE N. KUCERA
KELLOGG, HUBER, HANSEN,
TODD, EVANS & FIGEL,
P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

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APPENDIX

STATUTORY AND REGULATORY PROVISIONS

42 U.S.C. § 300aa-11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) of this section with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa-12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and –

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and

(II) such person elects under section 300aa-21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa-21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa-16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) of this section for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) of this section for such injury or death.

(6) If a person brings a civil action after November 15, 1988[1] for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) of this section for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) of this section for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court is authorized to continue to receive, and forward,

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[1] So in original. Probably should be followed by a comma.

petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1) of this section, file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain –

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died –

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table –

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and

medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

42 U.S.C. § 300aa-12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa-11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa-11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of Title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa-11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) of this section shall afford all interested persons an opportunity to submit relevant, written information –

(A) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States

Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, Title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, Title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts[1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United

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[1] So in original. Probably should be a reference to the United States Court of Federal Claims.

States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa-11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa-11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of Title 28. Such rules shall –

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without

requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall –

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e) of this section.

(B) In conducting a proceeding on a petition a special master –

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information –

(I) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceed-

ing without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information –

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter –

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the

date of entry of the United States Claims Court's[1] judgment with such court of appeals.

(g) Notice

If –

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) of this section (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa-21(b) of this title or the petitioner may choose under section 300aa-21(b) of this title to have the petition remain before the special master or court, as the case may be.

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[1] So in original. Probably should be a reference to the United States Court of Federal Claims.

42 U.S.C. § 300aa-21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa-12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa-11 of this title shall file with the clerk of the United States Court of Federal Claims –

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations

on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa-11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa-11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if –

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa-12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa-12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa-12(d)(3)(C) or 300aa-12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa-12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa-12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa-11 of this title shall, except as provided in section 300aa-16(c) of this title, be

brought within the period prescribed by limitations of actions under State law applicable to such civil action.

42 U.S.C. § 300aa-22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows –

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

42 U.S.C. § 300aa-23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa-11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa-22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be

held liable for punitive damages unless the manufacturer engaged in –

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

21 C.F.R. § 601.12. Changes to an approved application.

(a) *General.* (1) As provided by this section, an applicant must inform the Food and Drug Administration (FDA) (see mailing addresses in § 600.2 of this chapter) about each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application(s).

(2) Before distributing a product made using a change, an applicant must assess the effects of the change and demonstrate through appropriate validation and/or other clinical and/or nonclinical laboratory studies the lack of adverse effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

(3) Notwithstanding the requirements of paragraphs (b), (c), and (f) of this section, an applicant must make a change provided for in those paragraphs in accordance with a regulation or guidance that provides for a less burdensome notification of the change (for example, by submission of a supplement that does not require approval prior to distribution of the product or in an annual report).

(4) The applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling change implemented in accordance with paragraphs (f)(1) and (f)(2) of this section.

(5) A supplement or annual report must include a list of all changes contained in the supplement or annual report. For supplements, this list must be provided in the cover letter.

(b) *Changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes).* (1) A supplement shall be submitted for any change in the product, production process, quality controls, equipment, facilities, or responsible personnel that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

(2) These changes include, but are not limited to:

(i) Except as provided in paragraphs (c) and (d) of this section, changes in the qualitative or quantitative formulation, including inactive ingredients, or in the specifications provided in the approved application;

(ii) Changes requiring completion of an appropriate human study to demonstrate the equivalence of the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product;

(iii) Changes in the virus or adventitious agent removal or inactivation method(s);

(iv) Changes in the source material or cell line;

(v) Establishment of a new master cell bank or seed; and

(vi) Changes which may affect product sterility assurance, such as changes in product or component sterilization method(s), or an addition, deletion, or substitution of steps in an aseptic processing operation.

(3) The applicant must obtain approval of the supplement from FDA prior to distribution of the product made using the change. Except for submissions under paragraph (e) of this section, the following shall be contained in the supplement:

(i) A detailed description of the proposed change;

(ii) The product(s) involved;

(iii) The manufacturing site(s) or area(s) affected;

(iv) A description of the methods used and studies performed to evaluate the effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product;

(v) The data derived from such studies;

(vi) Relevant validation protocols and data; and

(vii) A reference list of relevant standard operating procedures (SOP's).

(4) An applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship on the applicant. Such a supplement and its mailing cover should be plainly marked: "Prior Approval Supplement-Expedited Review Requested."

(c) *Changes requiring supplement submission at least 30 days prior to distribution of the product made using the change.* (1) A supplement shall be submitted for any change in the product, production process, quality controls, equipment, facilities, or responsible personnel that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may

relate to the safety or effectiveness of the product. The supplement shall be labeled "Supplement–Changes Being Effected in 30 Days" or, if applicable under paragraph (c)(5) of this section, "Supplement–Changes Being Effected."

(2) These changes include, but are not limited to:

(i) [Reserved]

(ii) An increase or decrease in production scale during finishing steps that involves different equipment; and

(iii) Replacement of equipment with that of similar, but not identical, design and operating principle that does not affect the process methodology or process operating parameters.

(iv) Relaxation of an acceptance criterion or deletion of a test to comply with an official compendium that is consistent with FDA statutory and regulatory requirements.

(3) Pending approval of the supplement by FDA, and except as provided in paragraph (c)(5) of this section, distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA. The information listed in paragraph (b)(3)(i) through (b)(3)(vii) of this section shall be contained in the supplement.

(4) If within 30 days following FDA's receipt of the supplement, FDA informs the applicant that either:

(i) The change requires approval prior to distribution of the product in accordance with paragraph (b) of this section; or

(ii) Any of the information required under paragraph (c)(3) of this section is missing; the applicant

shall not distribute the product made using the change until FDA determines that compliance with this section is achieved.

(5) In certain circumstances, FDA may determine that, based on experience with a particular type of change, the supplement for such change is usually complete and provides the proper information, and on particular assurances that the proposed change has been appropriately submitted, the product made using the change may be distributed immediately upon receipt of the supplement by FDA. These circumstances may include substantial similarity with a type of change regularly involving a "Supplement–Changes Being Effected" supplement or a situation in which the applicant presents evidence that the proposed change has been validated in accordance with an approved protocol for such change under paragraph (e) of this section.

(6) If the agency disapproves the supplemental application, it may order the manufacturer to cease distribution of the products made with the manufacturing change.

(d) *Changes to be described in an annual report (minor changes).* (1) Changes in the product, production process, quality controls, equipment, facilities, or responsible personnel that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product shall be documented by the applicant in an annual report submitted each year within 60 days of the anniversary date of approval of the application. The Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation

and Research, may approve a written request for an alternative date to combine annual reports for multiple approved applications into a single annual report submission.

(2) These changes include, but are not limited to:

(i) Any change made to comply with a change to an official compendium, except a change described in paragraph (c)(2)(iv) of this section, that is consistent with FDA statutory and regulatory requirements.

(ii) The deletion or reduction of an ingredient intended only to affect the color of the product, except that a change intended only to affect Blood Grouping Reagents requires supplement submission and approval prior to distribution of the product made using the change in accordance with the requirements set forth in paragraph (b) of this section;

(iii) An extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the application;

(iv) A change within the container closure system for a nonsterile product, based upon a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium;

(v) A change in the size and/or shape of a container containing the same number of dosage units for a nonsterile solid dosage form product, without a change from one container closure system to another;

(vi) The addition by embossing, debossing, or engraving of a code imprint to a solid dosage form biological product other than a modified release dosage form, or a minor change in an existing code imprint; and

(vii) The addition or revision of an alternative analytical procedure that provides the same or increased assurance of the identity, strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application, or deletion of an alternative analytical procedure.

(3) The following information for each change shall be contained in the annual report:

(i) A list of all products involved; and

(ii) A full description of the manufacturing and controls changes including: the manufacturing site(s) or area(s) involved; the date the change was made; a cross-reference to relevant validation protocols and/or SOP's; and relevant data from studies and tests performed to evaluate the effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.

(iii) A statement by the holder of the approved application or license that the effects of the change have been assessed.

(4) The applicant shall submit the report to the FDA office responsible for reviewing the application. The report shall include all the information required under this paragraph for each change made during the annual reporting interval which ends on the anniversary date in the order in which they were implemented.

(e) An applicant may submit one or more protocols describing the specific tests and validation studies and acceptable limits to be achieved to demonstrate the lack of adverse effect for specified types of manufacturing changes on the identity, strength, quality,

purity, or potency of the product as they may relate to the safety or effectiveness of the product. Any such protocols, or change to a protocol, shall be submitted as a supplement requiring approval from FDA prior to distribution of the product which, if approved, may justify a reduced reporting category for the particular change because the use of the protocol for that type of change reduces the potential risk of an adverse effect.

(f) *Labeling changes.* (1) Labeling changes requiring supplement submission–FDA approval must be obtained before distribution of the product with the labeling change. Except as described in paragraphs (f)(2) and (f)(3) of this section, an applicant shall submit a supplement describing a proposed change in the package insert, package label, container label, or, if applicable, a Medication Guide required under part 208 of this chapter, and include the information necessary to support the proposed change. An applicant cannot use paragraph (f)(2) of this section to make any change to the information required in § 201.57(a) of this chapter. An applicant may report the minor changes to the information specified in paragraph (f)(3)(i)(D) of this section in an annual report. The supplement shall clearly highlight the proposed change in the labeling. The applicant shall obtain approval from FDA prior to distribution of the product with the labeling change.

(2) *Labeling changes requiring supplement submission–product with a labeling change that may be distributed before FDA approval.* (i) An applicant shall submit, at the time such change is made, a supplement for any change in the package insert, package label, or container label to reflect newly acquired information, except for changes to the package insert

required in § 201.57(a) of this chapter (which must be made under paragraph (f)(1) of this section), to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter;

(B) To add or strengthen a statement about abuse, dependence, psychological effect, or overdosage;

(C) To add or strengthen an instruction about dosage and administration that is intended to increase the safety of the use of the product; and

(D) To delete false, misleading, or unsupported indications for use or claims for effectiveness.

(E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the product that FDA specifically requests be submitted under this provision.

(ii) Pending approval of the supplement by FDA, the applicant may distribute a product with a package insert, package label, or container label bearing such change at the time the supplement is submitted. The supplement shall clearly identify the change being made and include necessary supporting data. The supplement and its mailing cover shall be plainly marked: "Special Labeling Supplement–Changes Being Effected."

(3) *Labeling changes requiring submission in an annual report.* (i) An applicant shall submit any final printed package insert, package label, container label, or Medication Guide required under part 208 of this chapter incorporating the following changes in

an annual report submitted to FDA each year as provided in paragraph (d)(1) of this section:

(A) Editorial or similar minor changes;

(B) A change in the information on how the product is supplied that does not involve a change in the dosage strength or dosage form;

(C) A change in the information specified in § 208.20(b)(8)(iii) and (b)(8)(iv) of this chapter for a Medication Guide; and

(D) A change to the information required in § 201.57(a) of this chapter as follows:

(*1*) Removal of a listed section(s) specified in § 201.57(a)(5) of this chapter; and

(*2*) Changes to the most recent revision date of the labeling as specified in § 201.57(a)(15) of this chapter.

(E) A change made pursuant to an exception or alternative granted under § 201.26 or § 610.68 of this chapter.

(ii) The applicant may distribute a product with a package insert, package label, or container label bearing such change at the time the change is made.

(4) *Advertisements and promotional labeling.* Advertisements and promotional labeling shall be submitted to the Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research in accordance with the requirements set forth in § 314.81(b)(3)(i) of this chapter, except that Form FDA-2567 (Transmittal of Labels and Circulars) or an equivalent form shall be used.

(5) The submission and grant of a written request for an exception or alternative under § 201.26 or

§ 610.68 of this chapter satisfies the requirements in paragraphs (f)(1) through (f)(2) of this section.

(6) For purposes of paragraph (f)(2) of this section, information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

(g) *Failure to comply.* In addition to other remedies available in law and regulations, in the event of repeated failure of the applicant to comply with this section, FDA may require that the applicant submit a supplement for any proposed change and obtain approval of the supplement by FDA prior to distribution of the product made using the change.

(h) *Administrative review.* Under § 10.75 of this chapter, an applicant may request internal FDA review of FDA employee decisions under this section.

SUPPLEMENTAL BRIEF

No. 09-152

In the Supreme Court of the United States

RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES AND LEDERLE LABORATORIES,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITIONERS' SUPPLEMENTAL BRIEF ADDRESSED TO THE BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE* FILED IN *AMERICAN HOME PRODS CORP., D/B/A WYETH, ET AL., V. FERRARI, ET AL.* (08-1120)

JOHN T. BOUNDAS
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway
Suite 600
Houston, Texas
77017-5051
(713) 230-2200

COLLYN A. PEDDIE
Counsel of Record
for Petitioners
THE LAW OFFICES OF
COLLYN PEDDIE
440 Louisiana
Suite 1710
Houston, Texas 77002-1689
(713) 422-1205

LEGAL PRINTERS LLC, Washington DC • 202-747-2400 • legalprinters.com

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 ["Vaccine Act" or "the Act"] expressly preempts certain design defect claims against vaccine manufacturers but only "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1); A-104.

The Question Presented is

Whether the Third Circuit erred in holding that, contrary to its plain text and the decisions of this Court, Section 22(b)(1) preempts all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not?

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INTRODUCTION

Responding to this Court's request, the Solicitor General has filed a brief on behalf of the United States in *American Home Prods Corp., d/b/a Wyeth, et al., v. Ferrari, et al.*, No. 08-1120. In it, the government agrees with all parties here and petitioners in *Ferrari* that the question of the proper interpretation of Section 22(b)(1) of the Vaccine Act, central to both cases, is of paramount national importance and arises from a direct, mature, and irreconcilable conflict between the decisions of the Georgia Supreme Court and Third Circuit in this case.

Although the Solicitor General's brief was filed in *Ferrari*, the government correctly concludes that ***this*** case provides the better vehicle for resolving the conflict and urges this Court to grant *certiorari* here. Petitioners respectfully ask this Court to take this part of the Solicitor General's advice and grant *certiorari* in this case.

While the government correctly identifies the ***issue*** in dispute, it does not present this Court with a question that will fully resolve it. Instead, it asks the Court to decide only whether Section 22(b)(1) preempts ***some*** design defect claims. This Court need not do so since all parties agree that the provision expressly preempts some design defect claims.

The critical question here, however, is the ***scope*** of the Vaccine Act's displacement of state law: whether, contrary to the Act's plain text, well-established rules of statutory construction, and the decisions of this Court, Section 22(b)(1) broadly preempt ***all*** vaccine

design defect claims, whether a vaccine's side effects were unavoidable or not? Petitioners' question presented properly focuses on Section 22(b)(1)'s preemptive scope, a question that remains of great national import.

Because the government inappropriately conflates the question of whether Section 22(b)(1) expressly preempts some design defect claims and the scope of that preemption, it avoids applying to their resolution the constitutional and statutory construction principles this Court reaffirmed in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), and *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008). Instead, the government construes Section 22(b)(1) without mentioning the presumption against preemption or its mandate that only "clear and manifest" expressions of Congressional intent can overcome it, or the principles that Congressional silence is evidence of intent ***not*** to preempt, and that express preemption clauses should ordinarily be construed narrowly, in a manner that ***disfavors*** preemption.

The Solicitor General's interpretation of Section 22(b)(1) is, therefore, fundamentally at odds with this Court's approach to resolving preemption questions and casts doubt on principles this Court reaffirmed just a year ago. Unless this Court grants *certiorari* here, those doubts will remain. The Solicitor General's brief therefore provides this Court with a cautionary tale and an additional reason to grant *certiorari*: to resolve the conflict over Section 22(b)(1)'s preemptive scope in a manner that preserves this Court's rulings in *Levine* and *Altria* and the essential guidance they provide to lower courts.

STATEMENT OF THE CASE

Petitioners agree with the Solicitor General that this Court should grant *certiorari* but disagree with the government's proposed resolution of the question presented, in part, because it is grounded in incomplete or incorrect factual information.

For example, the Solicitor General describes a unrealistically streamlined procedure in which injured children who received vaccines listed on the Vaccine Injury Table are freed from ordinary evidentiary burdens and "ensur[ed] that compensation is potentially available whenever tort remedies are preempted." Brief of the United States as *Amicus Curiae* ["U.S. Brief"] at 13. That is not the case for children, like Hannah Bruesewitz, whose injuries are ***not*** listed on the Table.[1] Instead, Hannah's family had to prove that her injuries were "caused in fact" by the vaccine she received, a standard far ***higher*** than they would have faced in state court.[2]

The Solicitor General also makes the startling and unsupported assertion that "most vaccines work by introducing ***a harmless substance*** (such as a partial or inactivated ***virus or toxin***) . . ." U.S. Brief at 19 (emphasis supplied). While many vaccines are safe for many people who receive them, no one can responsibly

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[1]In one confusing footnote, the Solicitor General implies that, if an injury is not listed on the Vaccine Injury Table, it is not preempted. *See* U.S. Brief at n.4. Would that that were true.

[2]*See, e.g., Andreu v. Sec'y of HHS*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) ("causation in fact" established for whole-cell DTP vaccine and Hannah's type of injury).

or accurately claim that vaccine antigens, which include viruses and other ***toxins***, are harmless.[3] Were that the case, Wyeth's whole-cell DTP vaccine would still be on the market, the Vaccine Act would be unnecessary, and Hannah Bruesewitz would be preparing for her prom instead of a lifetime of painful and terrifying seizures.

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[3] *See, e.g., Graham v. Wyeth Labs.*, 906 F.2d 1399, 1403 (10th Cir.), *cert. denied*, 498 U.S. 981 (1990) ("because the whole cell vaccine ***retains its poisonous qualities***, it is neurotoxic and can cause adverse reactions which may be mild or severe") (emphasis supplied).

REASONS FOR GRANTING THE PETITION

I. The Solicitor General and All Parties Agree That a Direct, Mature, and Irreconcilable Conflict Exists Over the Meaning of Section 22(b)(1), a Recurring Question of National Importance, and That This Case Is the Proper Vehicle to Resolve It.

All parties and the Solicitor General agree that *certiorari* is warranted here. In particular, the Solicitor General rightly concludes that "the Georgia court's decision [in *Ferrari*] squarely conflicts with" the Third Circuit's decision here. The government likewise finds the question presented "pressing," posing public health risks and creating unacceptable uncertainty, and that further percolation of the issue in the lower courts will not assist this Court. *See* U.S. Brief at 7, 17. The government therefore concludes that "the issue warrants this Court's review." *Id.* Because of mootness concerns in *Ferrari*, however, the Solicitor General urges this Court to grant the petition in ***this*** case, which presents the same question. *Id.*

While Petitioners do not agree with all of the reasons the Solicitor General advances, Petitioners join the government in asking this Court to grant their petition for writ of *certiorari*.

II. Petitioners Correctly State the Question Presented. The Solicitor General Does Not.

The Solicitor General asks this Court to decide whether Section 22(b)(1) "preempts state law claims against manufacturers based on alleged defects in the design of a vaccine subject to the Act." U.S. Brief at (1). All parties agree, however, that Section 22(b)(1) expressly preempts ***some*** design defect claims but only when it is found that "the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." A-104.

In *Altria*, this Court explained that, simply because "a federal law contains an express pre-emption clause, it does not immediately end the inquiry because ***the question of the substance and scope of Congress' displacement of state law still remains*** . . ." 129 S. Ct. at 543 (emphasis supplied). Thus, the question presented here is the ***scope*** of Section 22(b)(1)'s displacement of state law and whether it preempts ***all*** vaccine design defect claims, even when the vaccine's side effects could have been avoided by using a safer alternative vaccine.[4] To answer that question, this Court must use the analytical framework it reaffirmed in *Altria*.

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[4]In fact, the Solicitor General later admits that "the task therefore is to 'identify the domain expressly preempted by'" Section 22(b)(1). U.S. Brief at 8 (quoting *Medtronic v. Lohr*, 518 U.S. 470, 484 (1996)).

> Our inquiry into the scope of a statute's pre-emptive effect is guided by the rule that '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case' . . . When addressing questions of express or implied pre-emption, we begin our analysis 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the ***clear and manifest purpose of Congress***.' . . . That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States . . . ***Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'***[5]

By asking only whether Congress intended any preemption at all, the Solicitor General sidesteps this inquiry. For that reason, the precision of the question presented is critical in this case.

All parties and the government agree that the principal issue here is the scope of Section 22(b)(1)'s preemption of state law; therefore, the question presented should focus on language that delimits its preemptive scope. Because Petitioners' question presented is more precise, clear, and focused than the one offered by the Solicitor General, it merits this Court's review and resolution.

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[5] 129 S. Ct. at 543 (citations omitted) (emphasis supplied); *see Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

III. Although Incorrect, the Solicitor General's Proposed Resolution of the Question Presented Highlights Important Additional Reasons Why This Court Should Grant *Certiorari*.

By not mentioning or applying the presumption against preemption, *Levine*'s "clear and manifest" standard for overcoming it, its holding that Congressional silence evinces intent ***not*** to preempt, or *Bates'* rule for narrowly construing express preemption clauses, all of which are applicable here, the Solicitor General interprets Section 22(b)(1) in a manner that is inconsistent with this Court's approach to resolving preemption questions and at odds with each of these principles.[6] Thus, the Solicitor General's interpretation itself provides additional reasons why this Court should grant *certiorari* here: to resolve the conflict here in a manner that reaffirms these principles and preserves this Court's rulings in *Levine* and *Altria*.

For example, the Solicitor General rejects the *Ferrari* court's narrower interpretation of Section 22(b)(1) and its assumption that "if Congress had intended to bar all design defect liability, it could have said so more clearly." U.S. Brief at 9. In interpreting Section 22(b)(1), however, the *Ferrari* court relied squarely upon the presumption against preemption

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[6]By bypassing this Court's recent preemption jurisprudence, the Solicitor General casts doubt upon the administration's ***own*** preemption policy. *See* Memorandum to Heads of Executive Departments and Agencies from Barack Obama, President, May 20, 2009, *available at* http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/.

and this Court's recent preemption jurisprudence. *See American Home Prods Corp., d/b/a Wyeth, et al., v. Ferrari, et al.*, 668 S.E.2d 236, 242 (Ga. 2008) (citing *Bates*, 544 U.S. at 449). To hold as the Solicitor General recommends, this Court would have to ignore that presumption too. Moreover, this Court would also have to ignore *Bates*' and *Altria*'s instruction that, under that presumption, where, as here, there are two plausible interpretations of an express preemption clause, the Court must adopt the one that disfavors preemption.[7] Although the government posits "what the best reading of the actual language is," U.S. Brief at 9, it does so without acknowledging or adhering to these bedrock principles for interpreting preemption provisions.

Because the government does not mention the presumption against preemption, the Solicitor General also does not address the "clear and manifest" expression of intent necessary to overcome it. The inconclusive Congressional statements the government supplies, however, do not rise to the level of the "clear and manifest" showing this Court required in *Levine*.

The Solicitor General's reference to Congress' reliance on comment k similarly fails to provide the necessary showing of "clear and manifest" Congressional intent to preempt all vaccine design

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[7] *Altria*, 129 S. Ct. at 543; *Bates*, 544 U.S. at 449. The Solicitor General's attempt to interpret Section 22(b)(1)'s conditional language to apply only to manufacturing defects and labeling, U.S. Brief at 9, would abrogate this rule and is belied by the plain wording of Section 22(b)(1) itself, comment k's own language, and substantial contrary jurisprudence governing comment k. *See, e.g., Amore*, 748 F. Supp. at 854.

defect claims. In fact, it shows the opposite. For example, the Solicitor General relies heavily on the fact that, under RESTATEMENT (SECOND) OF TORTS § 402A, comment k (1965), a source for Section 22(b)(1), the manufacturer of a drug found "unavoidably unsafe" is freed from certain liability for design defects. Petitioners agree. The majority of states, however, embrace the same case-by-case approach for determining when that drug will be considered "unavoidably unsafe" under comment k that the Solicitor General rejects here.[8] In those states, drug manufacturers, including respondents here, routinely bear the burden to prove that their drugs are unavoidably unsafe, that is, that there are no safer alternatives, to demonstrate that their products fall under comment k's protection. *See, e.g., Patten v. Lederle Labs.*, 676 F. Supp. 233, 237 (D. Utah 1987).

The Solicitor General also implies that comment k provides blanket immunity for all prescription drugs. It does not.[9] To the contrary, a blanket exception to strict liability for all prescription drugs was proposed at the American Law Institute meeting where section

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[8] *See, e.g., Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000) ("the majority of jurisdictions that have adopted comment *k.* apply it on a case-by-case basis, believing that societal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity").

[9] *See, e.g., Patten*, 676 F. Supp. at 236; *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987), *cert. denied*, 485 U.S. 942 (1988).

402A and comment k were adopted, ***but the proposal was rejected.***[10]

This Court cannot rely upon ambiguous legislative statements or incomplete descriptions of source law to find preemption under the "clear and manifest" standard it reaffirmed a year ago.

The Solicitor General's efforts to disregard salient legislative history are also in tension with this Court's other recent jurisprudence. To disregard a 1987 committee report's clear statements of Congress' intent ***not*** to define "unavoidability" as a matter of law,[11] this Court must assume, as the Solicitor General does, that the Act was fully enacted in 1986. It was not.

Even the Third Circuit found that "the compensation program ***and accompanying tort reforms*** [were] ***contingent upon the enactment of***

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[10]38 ALI Proc. 19, 90-98 (1961), *cited in Amore v. G.D. Searle & Co.*, 748 F. Supp. 845, 853-54 (S.D. Fla. 1990).

[11]The report states:

> [T]he codification of Comment (k) of the Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

H.R. REP. 100-391(I), at 691 (1987), *reprinted in* U.S.C.C.A.N. 2313-1, 2313-365; A-36.

a tax to provide funding for the compensation." A-36 (emphasis supplied). In fact, another court refused to consider passage of the liability limits even as evidence of Congress' intent until the tax was enacted. It explained, "this Act shall only take effect on the effective date of a tax enacted to provide funds for compensation paid under the Act." *Wack v. Lederle Labs.*, 666 F. Supp. 123, 127, n.1 (N.D. Ohio 1987). Without the ***1987*** Congressional vote then, the liability limits respondents seek to invoke here ***would never have gone into effect***.

District of Columbia v. Heller, 128 S. Ct. 2783, 2805 (2008), makes clear that the 1987 Committee Report cannot be discarded in this Court's analysis. Because Congress' 1987 vote to create an excise tax specifically to fund the vaccine program ***and*** to give life to the Act's preemption provisions was contingent upon express assurances that unavoidability under Section 22(b)(1) would be determined on a case-by-case basis, the 1987 legislative history cannot be considered "subsequent" and rejected as such.

Whether this Court gives the 1987 Committee Report full effect or not, however, its existence surely precludes a finding of Congress' "clear and manifest" intent to preempt all vaccine design defect claims.

CONCLUSION

For the reasons stated, this Court should grant the petition for writ of *certiorari*.

Respectfully submitted,

Collyn A. Peddie
Counsel of Record
THE LAW OFFICES OF
COLLYN PEDDIE
440 Louisiana, Suite 1710
Houston, Texas 77002-1689
Telephone: (713) 422-1205
Facsimile: (713) 844-3755

John T. Boundas
WILLIAMS KHERKHER
HART BOUNDAS, LLP
8441 Gulf Freeway,
Suite 600
Houston, Texas 77017
Telephone: (713) 230-2200
Facsimile: (713) 643-6226

Counsel for Petitioners,
Russell, Robalee, and Hannah
Bruesewitz

AMICUS CURIAE BRIEF

No. 09-152

In the Supreme Court of the United States

RUSSELL BRUESEWITZ, ET AL., PETITIONERS

v.

WYETH, INC., FKA WYETH LABORATORIES, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

NEAL KUMAR KATYAL
Acting Solicitor General
Counsel of Record

TONY WEST
Assistant Attorney General

EDWIN S. KNEEDLER
Deputy Solicitor General

BENJAMIN J. HORWICH
Assistant to the Solicitor General

MICHAEL S. RAAB
IRENE M. SOLET
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

MARK B. CHILDRESS
Acting General Counsel

DAVID BENOR
Associate General Counsel for Public Health

EMILY MARCUS LEVINE
Senior Attorney

ANNA LORAINE JACOBS
Attorney
Department of Health and Human Services
Washington, D.C. 20201

QUESTION PRESENTED

The National Childhood Vaccine Injury Act of 1986 provides that "[n]o vaccine manufacturer shall be liable in a civil action" for any injury that "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1). The question presented is whether that provision preempts state law claims against a vaccine manufacturer based on alleged defects in the design of a vaccine subject to the Act.

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In the Supreme Court of the United States

No. 09-152

RUSSELL BRUESEWITZ, ET AL., PETITIONERS

v.

WYETH, INC., FKA WYETH LABORATORIES, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

INTEREST OF THE UNITED STATES

This case concerns the limitations that Congress placed on tort remedies in the National Childhood Vaccine Injury Act of 1986. The Secretary of Health and Human Services (Secretary or HHS) is responsible under the Act and other laws for promoting the development, supply, and widespread use of safe, pure, and potent vaccines, and is the respondent to petitions for compensation under the Act. At the Court's invitation, the United States filed an amicus brief at the petition stage in *American Home Products Corp.* v. *Ferrari*, petition for cert. pending, No. 08-1120 (filed Mar. 5, 2009), which presents the same question as this case.

STATEMENT

1. The National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (42 U.S.C. 300aa-1 *et seq.*), was enacted in response to "two overriding concerns": "the inadequacy —from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of [a tort-based] approach to compensating those who have been damaged by a vaccine," and "the instability and unpredictability of the childhood vaccine market" due to vaccine manufacturers' fear of tort liability. H.R. Rep. No. 908, 99th Cong., 2d Sess. 7 (1986) (*1986 Report*). Accordingly, the Act is designed to encourage "development and distribution of vaccines that will further enhance the public health," and to compensate individuals injured by such vaccines by means other than tort law. *Ibid.*

The Act furthers the public health by, *inter alia*, establishing a National Vaccine Program in HHS, implemented through a comprehensive plan to fund and coordinate vaccine research, licensing, and distribution, and to encourage public acceptance of immunization. 42 U.S.C. 300aa-1 to 300aa-3. The National Vaccine Advisory Committee established under the Act conducts studies and offers advice on research priorities and other matters. 42 U.S.C. 300aa-5. The Act also advances the public health through the collection and dissemination of information about vaccines, including adverse events potentially related to vaccine administration, and through promoting the development of safer vaccines. 42 U.S.C. 300aa-25 to 300aa-28.

The National Vaccine Injury Compensation Program (Compensation Program) established by the Act pays "no-fault" monetary awards to individuals found to be injured by vaccines subject to the Act. The Compensa-

tion Program is secured by the Vaccine Injury Compensation Trust Fund (Trust Fund) which is supported by an excise tax on each vaccine dose. 42 U.S.C. 300aa-10 to 300aa-19; 26 U.S.C. 4131, 9510. The Compensation Program covers categories of vaccines that have been formally recommended for routine administration to children by the Centers for Disease Control and Prevention (CDC), 42 U.S.C. 300aa-14(e)(2) and (2)(A); vaccines in those categories are, almost universally (see note 6, *infra*), licensed by the Food and Drug Administration (FDA) as biological products, see Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*; 42 U.S.C. 262; 21 C.F.R. Pts. 600-601.

To receive compensation for a vaccine-related injury or death, the injured party (or his legal representative) must file a petition in the Court of Federal Claims (CFC), naming the Secretary as respondent. 42 U.S.C. 300aa-11(a), 300aa-12(a) and (b). The claimant must show by a preponderance of the evidence that he received a vaccine listed on the Vaccine Injury Table (Table), 42 C.F.R. 100.3, and suffered a corresponding listed injury, or that a vaccine listed on the Table in fact caused or significantly aggravated any injury. 42 U.S.C. 300aa-11(c), 300aa-13(a). The claimant need not establish any defect in the vaccine, any fault by the manufacturer, or even the identity of the manufacturer.

A petition for compensation is initially heard by a special master, whose decision is reviewable by the CFC, and in turn by the Federal Circuit. 42 U.S.C. 300aa-12(c)-(f). Relative to the tens of millions of childhood vaccine doses administered annually, the number of petitions filed in the CFC is very small—reflecting the extraordinary safety of the covered vaccines. Since the first few years of the Compensation Program (which

saw several thousand claims for injuries that pre-dated the effective date of the Act), there typically have been 100 to 200 ordinary claims filed annually.[1] In the past decade, more than half of those claims have been compensated through settlement or a CFC decision, with an average award of approximately $836,000. See Health Res. & Servs. Admin., HHS, *National Vaccine Injury Compensation Program Post-1988 Statistics Report* (July 14, 2010) (*Statistics Report*) http://www.hrsa.gov/vaccinecompensation/docs/StatisticsReport.pdf. The CFC compensates for current and future medical costs; costs of rehabilitation, counseling, and special education; lost earning capacity; and pain and suffering. 42 U.S.C. 300aa-15(a). To ensure representation, the Compensation Program awards reasonable attorneys' fees and costs (including expert witness fees) even if there is no award to the claimant, provided the petition was brought in good faith and with a reasonable basis. 42 U.S.C. 300aa-15(e).

The Act forbids a claimant from immediately resorting to a civil action for damages against the vaccine's manufacturer. Rather, he must first file a petition under the no-fault scheme and seek a judgment from the CFC. 42 U.S.C. 300aa-11(a)(2)-(3). If the claimant elects to reject that judgment (and any award), or withdraws his petition after the special master or CFC fails to render a judgment within specified time periods, then

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[1] Not counted among these ordinary claims are more than 5600 petitions—about 5000 still pending—that assert a causal link between certain vaccines and autism spectrum disorders. Those cases have been consolidated before the CFC in the Omnibus Autism Proceeding (OAP). See U.S. Pet. Stage Amicus Br. at 4-5, *American Home Prods. Corp.* v. *Ferrari*, petition for cert. pending, No. 08-1120 (filed Mar. 5, 2009).

he may bring a civil action against the manufacturer. 42 U.S.C. 300aa-11(a)(2)(A), 300aa-21(a)-(b).

Such civil actions are governed by state law, subject to several limitations in the Act. See 42 U.S.C. 300aa-22 (Section 22). Among these limitations is the provision at issue here:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. 300aa-22(b)(1) (Section 22(b)(1)). Under 42 U.S.C. 300aa-22(e) (Section 22(e)), a State is barred from further limiting such claims: "No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part."

3. Petitioners' daughter experienced seizures after her third dose of a diphtheria-tetanus-pertussis (DTP) vaccine. She ultimately suffered residual seizure disorder and developmental delay. Pet. App. A6. Petitioners pursued a timely but unsuccessful petition for compensation in the CFC, and rejected the CFC's judgment pursuant to 42 U.S.C. 300aa-21(a)(1). J.A. 1-2. They then sued the vaccine's manufacturer—respondents in this Court—in Pennsylvania state court, alleging (as relevant here) that toxins inherent in the vaccine's design caused their daughter's injuries. Following removal of the case, the district court granted summary judgment for respondents, holding that the Act pre-

empted petitioners' design-defect claims. See Pet. App. A9-A11.

The court of appeals affirmed. Pet. App. A1-A52. The court noted that Section 22(b)(1)'s bar "primarily relates to design defect claims," because the other types of products liability claims (*i.e.*, for manufacturing or labeling defects) are dealt with in the "subordinate clause introduced by 'even though.'" *Id.* at A27. The court rejected petitioners' position that the term "unavoidable" called for a "case-by-case analysis of whether particular vaccine side effects are avoidable," because that reading "does not bar any design defect claims" and instead would make "every design defect claim * * * subject to evaluation by a court." *Id.* at A29. The Court further concluded that the Act preempts all design defect claims irrespective of whether they sound in negligence or strict liability. *Id.* at A31-A36.

SUMMARY OF ARGUMENT

Congress intended, through the express preemption language of Section 22(b)(1), to exempt vaccine manufacturers from tort liability for the designs of their FDA-licensed vaccines, while offering, through other provisions of the Vaccine Act, compensation to the injured. The result of the Act is a robust federal framework that encourages the development of even safer vaccines and that provides compensation where Congress deemed it appropriate.

A. Section 22(b)(1) bars claims against a vaccine manufacturer for injuries that "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The text thus identifies injuries traceable to two familiar types of product defects (manu-

facturing and labeling defects) as avoidable, while designating what remains (injuries from side effects inherent in the vaccine's design) as unavoidable. That latter category of injury is at issue here, and Section 22(b)(1) bars civil damage suits against manufacturers on such a theory.

Section 22(b)(1) was drawn, in part, from Comment k to Section 402A of the Restatement (Second) of Torts, which makes the same distinction among theories of product liability. Comment k concerns "[u]navoidably unsafe" products, which are those that "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts (Restatement) § 402A cmt. k (Comment k) at 353 (1965) (emphasis omitted). Under Comment k, such an unavoidably unsafe product—which the Act in effect deems vaccines to be—is not defective in its design, though it still exposes its manufacturer to liability for manufacturing and labeling defects. The legislative history of Section 22(b)(1) makes the same distinction: An injured vaccine recipient who "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper warnings should pursue recompense in the compensation system, not the tort system." *1986 Report* 26.

Congress enacted the Vaccine Act (and Section 22(b)(1) in particular) in significant part to alleviate the large and potentially unknowable tort liability that vaccine manufacturers faced. That exposure had increasingly led manufacturers to cease production of vital vaccines, which in turn threatened vaccine shortages and the resurgence of preventable disease. On petitioners' reading, Section 22(b)(1) would fail of its purpose, be-

cause it would offer vaccine manufacturers no more protection than the limited state law defense they already enjoyed under the narrowest reading of Comment k. Indeed, petitioners' reading would expose vaccine manufacturers to *greater* tort liability than they faced before the Act, because Section 22(e), which preempts state laws restricting tort remedies that are not barred by the Act, would strip manufacturers of strong design-defect defenses offered by some state laws.

B. The structure of the Vaccine Act as a whole, and the regulatory background against which it was enacted, confirm Congress's strategy of removing design-based claims from the tort system, and relying instead on a panoply of federal programs and regulations assuring safe vaccine design and on a no-fault compensation system offering a remedy to injured individuals.

Just like today, when the Vaccine Act was passed, all vaccines were subjected to a rigorous FDA licensing process, including some of the most thorough examinations and largest clinical trials that FDA utilizes. After licensing, a manufacturer may not alter its vaccine's design without prior FDA approval. Post-licensing safety monitoring of vaccines under the Act is more comprehensive than other classes of FDA-approved products because not only manufacturers but also health care providers are required to report adverse events. In addition, using authorities granted in the Act, HHS has established a strong partnership with health care organizations to give its researchers access to high-quality data for researching immunization safety questions. And the federal government conducts and funds more than $2 billion of vaccine research annually.

The Compensation Program, for its part, has fulfilled Congress's objective of establishing a comprehensive,

fast, and fair system for making awards to individuals injured by vaccines covered by the Act. In matters ranging from the burden of proof and rules of decision, through the availability of legal representation and discovery, to the remedies awarded, the Compensation Program is as favorable to claimants—and in some respects, decidedly more favorable—than the tort system. Because the Act is structured to ensure that compensation is available whenever tort remedies are preempted, those who are injured are not left without a remedy.

ARGUMENT

MANUFACTURERS MAY NOT BE HELD CIVILLY LIABLE FOR THE DESIGN OF A VACCINE SUBJECT TO THE ACT

A. Section 22's Text, Structure, Purpose, And History Show That It Preempts Claims Against Manufacturers Based On Vaccine Design

Section 22(b)(1) expressly preempts state law. See, *e.g.*, Pet. App. A20-A22. The task therefore is to "identify the domain expressly pre-empted." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 484 (1996) (citation omitted). The preemptive reach of Section 22(b)(1) turns on what Congress intended to convey by invoking the term of art "unavoidable." Petitioners contend that the term calls for a "case-specific" approach (Br. 35), under which a claim is not preempted if the plaintiff shows that the side effects could have been avoided by some alternative design. Br. 29. Respondents, however, are correct in their contention (Br. 24) that "unavoidable"—when read alongside the modifying phrase that follows it—forbids tort claims challenging a vaccine's design, but preserves claims asserting that the injury or death could have been avoided by proper preparation or proper directions and warnings.

1. Section 22's text and structure preempt claims based on vaccine design

a. Section 22(b)(1) bars claims against a vaccine manufacturer based on an injury or death that "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The subordinate "even though" clause following the word "unavoidable" singles out two of the familiar categories of product liability law: manufacturing defects (*i.e.*, claims that the vaccine was not "properly prepared") and labeling defects (*i.e.*, claims that the vaccine was not "accompanied by proper directions and warnings"). The modifying clause thus explicates the universe of side effects that are *not* "unavoidable"—those caused by manufacturing defects or improper labeling. Excluded from that clause is the remaining category of product liability claims—those alleged to result from the vaccine's FDA-licensed design. Under the Act, those side effects *are* "unavoidable." The result is that Section 22(b)(1) bars one theory of liability (design defect), while leaving in place two others (manufacturing and labeling defects), subject to other limitations in the Act.[2]

The Vaccine Act and related laws provide a clear standard for deciding whether a manufacturing defect exists and whether the vaccine was properly labeled. The vaccine's license, issued by FDA under 42 U.S.C. 262, speaks to those subjects in detail. See 21 C.F.R. 601.2(a). In addition, the Vaccine Act creates a presumption that a vaccine is properly labeled if the manu-

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[2] Section 22(b)(1)'s bar on claims challenging vaccine design is limited: it applies only to damage claims, only to vaccines on the Table, and only to claims against manufacturers.

facturer complied in all material respects with the FDCA, with 42 U.S.C. 262 (which concerns licensing of biological products), and with implementing regulations. 42 U.S.C. 300aa-22(b)(2). The Vaccine Act thus promotes safety by tying protection from liability to compliance with the comprehensive federal regulatory scheme. By contrast, nowhere does the Act or any other law offer a standard for design-defect claims. For example, for the plaintiff to prove the existence of a safer alternative vaccine, would the alternative vaccine simply have to be available in a lab somewhere? Or would it have to be available for sale? Must it have been licensed by FDA? Congress's silence on questions like those reinforces the conclusion based on the text of Section 22(b)(1) that Congress removed issues concerning the design of FDA-licensed vaccines from the tort system.

b. Petitioners argue (Br. 28-29) that "unavoidable" should be given a dictionary definition of "'incapable of being . . . prevented' or 'inevitable.'" That argument begs the question of what measures the Act contemplates a manufacturer can take to avoid side effects. A particular side effect might have been avoided by using an unlicensed, untested vaccine of unknown potency that exists only in a laboratory. Yet no one suggests the possibility of that kind of avoidance would be reason to hold a vaccine manufacturer liable. Rather, to understand what side effects are "unavoidable," the "[s]tatutory language must be read in context" because a word "gathers meaning from the words around it." *Jones* v. *United States*, 527 U.S. 373, 389 (1999) (citation omitted). Here, in the context of the subordinate "even though" clause that follows it, "unavoidable" refers to side effects that are inherent risks of the FDA-approved

vaccine even when it is properly manufactured and labeled.

Petitioners also rely (Br. 32) on the conditional nature of the phrase "if the injury or death resulted from side effects that were unavoidable." 42 U.S.C. 300aa-22(b)(1). That phrasing does not assist petitioners. The United States agrees that Section 22(b)(1) states a condition for non-liability; the dispute is over its content—*i.e.*, the meaning of "unavoidable."

Petitioners further suggest (Br. 39-40) that if Congress had intended to bar all liability based on vaccine design, it could have said so more clearly or in different words. But "it is always possible to construct through hindsight an alternate structure for a statute with alternative wording that would render it more clear." Pet. App. A28. Here, the import of Section 22(b)(1) is evident—on its own terms, and (as explained below) in the context of the structure and purposes of the Act as a whole. Relatedly, petitioners criticize respondents for "read[ing] * * * language out of the statute." Pet. Br. 40. That criticism misunderstands the text: the overall "if" clause specifies the condition under which a suit is barred by reference to alleged causes of the claimed injury, while the subordinate "even though" clause elaborates upon that condition by specifying that a manufacturer may be liable if its vaccine is not properly prepared and labeled. Ironically, *petitioners'* reading makes the "even though" phrase unnecessary. If injuries from defective design are "[]avoidable" within that word's plain meaning, then so too are injuries from mismanufacturing and insufficient labeling; there would be no purpose to singling out the latter categories in their own clause.

2. Section 22's purpose and legislative history show that Congress intended to preempt claims against manufacturers based on vaccine design

Section 22(b)(1) is integrally related to other provisions of the Act—such as those that demand government vigilance over vaccines at all stages from development through administration to the population at large, and those that award compensation to individuals who are injured by vaccines. See pp. 19-30, *infra*. Section 22(b)(1)'s purpose and legislative history illuminate how it fits with those provisions of the broader Act, and confirm that Congress intended that manufacturers would not be held liable for the designs of their vaccines.

a. The *1986 Report* explains (at 25-26) that the term "unavoidable" in Section 22(b)(1) was drawn from Comment k to Section 402A of the Restatement (Second) of Torts, which concerns "*[u]navoidably unsafe products*." Comment k at 353 (caption). Comment k recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and offers a vaccine as a prototypical example. *Ibid.* Under Comment k, such a product is "not defective" or "*unreasonably* dangerous" as a matter of law, and the seller cannot be held liable for the consequences of its use if it was "properly prepared and marketed" and accompanied by "proper warning." *Id.* at 354. Section 22(b)(1) adopts that special principle of non-liability.

The *1986 Report* states that the Committee "intends that the principle in Comment K regarding 'unavoidably unsafe' products * * * apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system." *1986 Report* 26. In other words, vaccines covered by the Act are categorically

deemed "unavoidably unsafe products," if properly prepared and labeled, and thus not subject to design-defect claims. Petitioners contend (Br. 30-31, 46) that this passage of the *1986 Report* and the use of "unavoidable" in the Act indicate that Congress wanted courts to (1) evaluate case-by-case whether a given vaccine was an unavoidably unsafe product, and then (2) apply on that basis either ordinary liability principles from Restatement § 402A, or else Comment k's special principle of non-liability for unavoidably unsafe products. That contention is mistaken. The Act relieves courts from the former task; the *1986 Report* explains (at 26) that "the principle * * * regarding 'unavoidably unsafe' products"—the principle of non-liability—should always apply if the vaccine has been properly manufactured and labeled.

The *1986 Report* goes on explicitly to tie Section 22(b)(1) to the Compensation Program, and to underscore the consequence of applying "the principle in Comment K * * * to the vaccines covered in the bill":

> Given the existence of the [no-fault] compensation system in this bill, * * * [v]accine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.

1986 Report 26.

b. An "overriding concern[]" that prompted the Act was fear of "instability and unpredictability of the childhood vaccine market" from the threat of large tort liabil-

ity. *1986 Report* 7. That concern lay at the heart of the Act's liability reform, and yet petitioners' reading would mean that Section 22(b)(1) would not address that problem. Critically, although some States in 1986 accorded vaccines categorical immunity, see Resp. Br. 43 n.25, and some States in 1986 conditioned the manufacturer's defense on a case-by-case showing that Comment k applied, see Pet. Br. 34 n.17, no State in 1986 left vaccine manufacturers without even the prospect of invoking Comment k case-by-case. Thus, on petitioners' view, Congress achieved *nothing* in Section 22(b)(1) because it preempts liability only for conduct that state tort law would never have held tortious in the first place. Respondents' view, by contrast, respects Congress's determination to address the burden of litigation and the threat of large and unpredictable tort judgments against vaccine manufacturers.

c. Petitioners also rely on language in a 1987 committee report that post-dated passage of the Act, and statements in hearings on the accompanying legislation. Br. 48-51 (citing, *inter alia*, H.R. Rep. No. 391, 100th Cong., 1st Sess. 691 (1987) (*1987 Report*)). According to that report, the codification of Comment k "was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe." *1987 Report* 691.

Neither the *1987 Report* nor statements in the hearings are persuasive authority for interpreting the Act as passed in 1986. Both were prepared after Section 22(b)(1) became law and therefore "could have had no

effect on the congressional vote." *District of Columbia* v. *Heller*, 128 S. Ct. 2783, 2805 (2008).[3]

Petitioners note (Br. 48, 51) that Section 22(b)(1) did not become effective until the Compensation Program was funded by the appropriations that were the subject of the *1987 Report*, and so "the 100th Congress had full power to reconsider the Act's liability provisions." But Congress always retains the power to repeal or amend a law. See, *e.g.*, *United States* v. *Winstar Corp.*, 518 U.S. 839, 873 & n.19 (1996) (plurality opinion). What matters is that the Members of Congress who voted in 1986 for the Act as a whole, and for the Compensation Program and Section 22(b)(1) in particular, did so with the understanding not of some later document or hearing testimony, but rather of the *1986 Report* that vaccine design should "not be the subject of liability in the tort system." *1986 Report* 26.

3. Section 22's dual preemption provisions reinforce the conclusion that petitioners' claims are preempted

Petitioners argue that their reading of Section 22(b)(1) comports with a background assumption that state police powers are not preempted. Br. 40-41 (citing *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538, 543 (2008)).

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[3] The *1987 Report* also states (at 691) that when the House Committee on Energy and Commerce considered the original Act in 1986, it rejected an amendment providing that "a manufacturer's failure to develop [a] safer vaccine was not grounds for liability." See *Markup Hearing on H.R. 5546 Before the House Comm. on Energy & Commerce*, 99th Cong., 2d Sess. 46-54 (1986) (rejecting amendment). But the proceedings within a single committee's markup session are likewise not an authoritative guide to what Congress understood and intended in passing a bill. Rather, "the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill." *Eldred* v. *Ashcroft*, 537 U.S. 186, 209 n.16 (2003) (citation omitted).

That argument is mistaken. To begin with, the text, structure, purpose, and history of the Act as a whole and Section 22(b)(1) in particular dispel any such assumption here. Moreover, such a background assumption cannot be productively invoked in light of the highly unusual structure of Section 22, which contains *two opposing* preemption provisions, Section 22(b)(1) and Section 22(e). Considered together, those provisions cast even more doubt on petitioners' reading. The former limits certain claims against manufacturers (to ensure a stable vaccine supply), while the latter bars state restrictions on plaintiffs' causes of action beyond the restrictions the Act imposes (to ensure adequate tort remedies).

Those provisions operate in tandem to provide, roughly, that claims forbidden by the Act are barred (irrespective of state law), and that claims not forbidden by the Act must be permitted to proceed (irrespective of state law). Consequently, whenever Section 22(b)(1) does not preempt a cause of action, Section 22(e) *does* preempt a state law barring such an action. Conversely, a holding that Section 22(b)(1) preempts a cause of action means that Section 22(e) does not have preemptive effect. Either way, some state laws are preempted; the only question is which ones.

Thus, if petitioners' view of Section 22(b)(1) prevailed, Section 22(e) would preempt state laws that give vaccine manufacturers more protection than mere case-by-case application of Comment k. For example, some States have statutory provisions that give vaccine manufacturers a stronger defense to design defect claims than would case-by-case application of Comment k. See, *e.g.*, Mich. Comp. Laws Ann. § 600.2946(5) (West 2003), discussed in *Taylor* v. *SmithKline Beecham Corp.*, 658 N.W.2d 127 (Mich. 2003) (defense based on FDA

approval);[4] Utah Code Ann. § 78B-6-703(2) (2008). Section 22(e) would also threaten States that have adopted Comment k by statute, to the extent interpretation of those statutes deviates from petitioners' view of Section 22(b)(1). See, *e.g.*, N.J. Stat. Ann. § 2A:58C-3(a) (West 2000).[5]

Thus, on petitioners' view, Congress not only did nothing to shield manufacturers from design defect claims (see p. 15, *supra*), but it preemptively forbade States from offering such protection. Ironically, the Act then would expose manufacturers to *greater* liability for their vaccine designs than they would face under state law alone. That is irreconcilable with Congress's "overriding concern[]" about "instability and unpredictability of the childhood vaccine market." *1986 Report* 7.

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[4] This statute was also the subject of *Warner-Lambert Co., LLC* v. *Kent*, 552 U.S. 440 (2008) (per curiam) (affirming by an equally divided Court).

[5] The preemptive effect of petitioners' position would be broader still if Section 22(e) reached not only positive law but common law as well, because it would abrogate the protection that vaccine manufacturers enjoy in many States under judicial decisions according categorical exemption of FDA-approved drugs from design-defect liability. See Resp. Br. 43 & n.25 (citing cases "categorically preclud[ing] design-defect claims against products like vaccines"). Indeed, contrary to the narrow reading of Section 22(e) they now advance, Pet. Br. 42-43, petitioners argued below that Section 22(e) required Pennsylvania law to recognize a strict liability cause of action for a vaccine design defect, even though its courts had refused to do so. See Dkt. 29 at 18-19; Pet. C.A. Reply Br. 10. That may not, however, be the best construction of Section 22(e). Cf. *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 63 (2002) (construing language similar to Section 22(b)(1) not to preempt state common law).

B. The Act's Overall Structure Confirms Section 22's Preemptive Effect

The federal government has a unique policy governing childhood vaccines, and that policy differs from those governing most pharmaceuticals and medical devices. In the Vaccine Act, Congress adopted an affirmative and comprehensive national policy favoring development and widespread administration of childhood vaccines. See 42 U.S.C. 300aa-2 (responsibilities of the National Vaccine Program). Section 22(b)(1) reflects Congress's judgment that holding manufacturers liable for the design of their vaccines would unacceptably undermine the Act and its animating policy. Instead, other features of the Act furnish substitutes for the tort system in promoting safety and providing compensation to injured vaccine recipients.

1. The Act is a central component of a statutory framework that creates proven incentives for improving vaccine safety

By design and in practice, the Vaccine Act, building upon preexisting laws that regulate vaccines, features close federal involvement in (1) ensuring that only safe, pure, and potent vaccines are brought to market, (2) identifying adverse events associated with vaccines on the market, and (3) funding and encouraging vaccine research and improvement. Indeed, the Act specifically commands the Secretary to "promote the development of childhood vaccines that result in fewer and less serious adverse reactions * * * and promote the refinement of such vaccines." 42 U.S.C. 300aa-27(a)(1).

a. Today, as in 1986, all vaccines covered by the Act and released to the market must first undergo the rigorous FDA licensing process for biological products. See

21 U.S.C. 301 *et seq.*; 42 U.S.C. 262; 21 C.F.R. Pts. 600-601; cf. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 317 (2008) ("Premarket approval is a rigorous process.") (internal quotation marks and citation omitted). New childhood vaccines in particular are put through some of the most thorough examinations and largest clinical trials of any FDA-approved product.

For example, development of new vaccines for rotavirus gasteroenteritis (a severe diarrheal disease) began in the early 1980s and, after clinical trials involving more than 130,000 participants, culminated in FDA licensing of the vaccines in 2006 and 2007. See H. Fred Clark et al., *Rotavirus Vaccines*, *in Vaccines* 719-720 (Stanley Plotkin et al. eds., 5th ed. 2008) (*Vaccines*); Roger I. Glass & Umesh D. Parashar, *The Promise of New Rotavirus Vaccines*, 354 New Eng. J. Med. 75, 76 (2006). FDA's Center for Biologics Evaluation and Research informs this Office that a typical vaccine license application takes thousands of hours to review, covers 40-80 volumes of data and information, and demands a team of 8-12 FDA personnel including medical officers, scientists, consumer safety officers, and inspectors. Once licensed and manufactured, each lot of vaccine must be rigorously tested before release. See 21 C.F.R. Pt. 610.[6]

A license reflects the detailed manufacturing process for the vaccine, as well as its labeling, container, and other matters. See 21 C.F.R. 601.2(a). A vaccine manufacturer may not alter the design of its vaccine without

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[6] The Act also covers an unlicensed vaccine undergoing FDA-regulated clinical trials that is in a category listed on the Table. In addition, some vaccines administered abroad to federal employees and their dependents would be covered by the Act, see 42 U.S.C. 300aa-11(c)(1)(B)(i)(II), but may not be subject to FDA regulation.

FDA's prior approval. See 21 C.F.R. 601.12(b) and (b)(2)(i). That also was true under regulations in effect when the Vaccine Act was passed; those required prior FDA approval of any "[i]mportant proposed changes," 21 C.F.R. 601.12 (1986), which included any design changes. Congress therefore could not have expected vaccine manufacturers to alter the designs of their vaccines unilaterally. The situation here thus differs materially from *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009), in which this Court concluded that the drug manufacturer could have unilaterally remedied a labeling defect using FDA's "Changes Being Effected" regulation, 21 C.F.R. 314.70(c). See *Levine*, 129 S. Ct. at 1196-1197.

Routine childhood vaccines typically have such a low rate of unavoidable serious side effects (sometimes numbering in the single digits per million doses) that they may not be discovered even in massive clinical trials. The Act therefore mandates stringent post-licensing monitoring by requiring that both vaccine manufacturers and health care providers report side effects (and other contraindicating reactions) to HHS through the Vaccine Adverse Event Reporting System (VAERS). 42 U.S.C. 300aa-25(b); see http://vaers.hhs.gov. Pediatricians and other children's health care providers are uniquely well-positioned to learn of and observe adverse events that occur after vaccination, and mandatory reporting by them makes post-approval monitoring of vaccines even more comprehensive than parallel systems applicable to drugs and non-vaccine biological products. Compare 42 U.S.C. 300aa-25(b) (vaccines), with 21 C.F.R. 600.80 (biological products, including vaccines); 21 U.S.C. 355(k)(1); and 21 C.F.R. 314.80 (drugs).

Because VAERS depends on self-reporting, however, its data alone are not sufficient for sound public health

policy decisions. VAERS data are instead used to trigger further investigation, often employing the Vaccine Safety Datalink (VSD). VSD, which was developed primarily on the authority of 42 U.S.C. 300aa-2(a)(7)-(8) and 300aa-27(a), is a partnership between the federal government and several private managed care organizations. The VSD project includes a database with high-quality medical and vaccination data on about 5.5 million patients annually, which is used by researchers affiliated with CDC and under CDC contract to investigate immunization safety questions. See CDC, *Vaccine Safety Datalink (VSD) Project*, http://www.cdc.gov/vaccinesafety/Activities/vsd.html (last modified Feb. 17, 2010).

Vaccine safety and innovation are also encouraged through government-funded and government-conducted research. The National Institutes of Health (NIH)—the primary federal agency charged with conducting and supporting biomedical research—reports funding each year about $1.7 billion of general vaccine research and an additional amount, totaling more than $500 million, on HIV/AIDS vaccine research. See NIH, *Estimates of Funding for Various Research, Condition, and Disease Categories*, http://report.nih.gov/rcdc/categories (last modified Mar. 23, 2010). The Act requires the Director of the National Vaccine Program to coordinate such funding and research activities throughout the government. See 42 U.S.C. 300aa-2(a)(1)-(2).

In addition, the determination of which vaccines are administered to children, and thus which are manufactured and sold, is strongly influenced by expert governmental and nongovernmental entities—such as the Public Health Service (PHS), CDC, the Advisory Committee on Immunization Practices (ACIP), and the American

Academy of Pediatrics (AAP). For example, in 1999 PHS, ACIP, and AAP expressed the view that it would be preferable not to expose children to even the small amounts of mercury in the vaccine preservative thimerosal, provided vaccine supply, safety, and potency could be maintained without its use.[7] Over the next three years, manufacturers developed and obtained licenses for thimerosal-free (or trace thimerosal) childhood vaccines, and ceased production of childhood vaccines containing thimerosal. Congress anticipated exactly this sort of process in, for example, recognizing CDC's key role in establishing vaccination recommendations. See 42 U.S.C. 300aa-14(e).

b. Events surrounding the withdrawal of the Rotashield vaccine illustrate how well this system functions in practice. Rotashield was licensed in late 1998 for immunization against rotavirus, which causes severe diarrheal disease. Clinical trials identified a slight—but not statistically significant—increase among recipients in incidents of intussusception, a form of bowel collapse. FDA therefore required as a condition of licensure that the manufacturer commit to post-licensing studies. CDC recommended the vaccine for routine administration to children in March 1999. CDC, *Recommended Childhood Immunization Schedule—United States, 1999*, 48 MMWR 12 (1999).

Out of the approximately 1.5 million doses administered between September 1998 and June 1999, VAERS reports identified ten incidents of intussusception. Those reports prompted CDC to initiate studies using

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[7] See, *e.g.*, AAP & PHS, *Thimerosal in Vaccines*, 48 Morbidity & Mortality Wkly. Rep. (MMWR) 563-565 (1999); ACIP, *Recommendations Regarding the Use of Vaccines that Contain Thimerosal as a Preservative*, 48 MMWR 996-998 (1999).

the VSD and other methods in June 1999, and the next month CDC recommended suspending use of Rotashield based on VAERS and VSD data. CDC, *Intussusception Among Recipients of Rotavirus Vaccine—United States, 1998-1999*, 48 MMWR 577 (1999). The manufacturer suspended distribution, and three months later it withdrew Rotashield altogether, explaining that it had "evaluated the additional cases of intussusception reported to VAERS as well as preliminary data from the ongoing epidemiological studies conducted by CDC [that] will be publicly discussed at [an] upcoming [ACIP] meeting." *Wyeth Lederle Vaccines Voluntarily Withdraws from the Market Its Rotavirus Vaccine RotaShield®*, PR Newswire, Oct. 15, 1999. CDC then formally withdrew its recommendation for routine use of rotavirus vaccine. CDC, *Withdrawal of Rotavirus Vaccine Recommendation*, 48 MMWR 1007 (1999). FDA revoked the Rotashield license, and research into other rotavirus vaccines continued, culminating in licensing several years later of new vaccines after broad clinical trials, see p. 20, *supra*.

Thus, in the space of about one year, a vaccine was licensed and recommended for routine administration, adverse events raised a concern, further studies were conducted, and the manufacturer withdrew the vaccine knowing the government and physician community were ready to respond. Tort litigation played no role in Rotashield's withdrawal; indeed, to the government's knowledge, no tort suit ever proceeded over a Rotashield injury. The Table was amended to add intussusception as an injury for rotavirus vaccine, 67 Fed. Reg. 48,558 (2002), and those injured received compensation.

c. Petitioners nonetheless assert (Br. 52-56) that imposing tort liability on vaccine designs will promote

the Act's goal of ensuring safe and potent vaccines. But unusual features about vaccines show that this is wrong; indeed, such liability could, perversely, stall innovations in safety. As noted above, the side effects of childhood vaccines can be so rare that they are not evident until millions of doses have been administered, meaning that a manufacturer may be unable realistically to assess its potential liability before marketing a vaccine. Public health would be undermined if manufacturers reacted by foregoing research and development of new vaccines.

As explained in our amicus brief (at 18-20) at the petition stage in *Ferrari*, *supra*, current research offers several examples of vaccine development strategies and techniques that promise significant advantages in safety and potency over currently marketed vaccines, but that could result in rare side effects that are currently unknown. Such side effects would, on petitioners' view, be "[]avoidable" if they were not associated with the form of the vaccine now on the market, and a basis for holding an innovative manufacturer liable. Coupled with federal vigilance over new vaccine designs, Section 22(b)(1) removes the tort system's disincentive to such vaccine innovation.

2. Congress established the Compensation Program as a sound substitute for the tort system

The Compensation Program has fulfilled Congress's related goal of establishing a "comprehensive and fair compensation system," *1986 Report* 25, that "work[s] faster and with greater ease than the civil tort system," *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995), and "goes far beyond even the most exp[a]nsive ruling issued by a court in a vaccine case," *1986 Report* 26. Congress saw the Compensation Program as the critical counter-

part to Section 22(b)(1)'s withdrawal of certain tort remedies. See *ibid.*

a. The Compensation Program is as favorable to claimants—and in some respects, decidedly more favorable—than the tort system. This is exactly what Cor gress envisioned:

- The Compensation Program is faster. Data from Congress's survey of vaccine tort suits in the early 1980s suggest that such suits took, on average, three to four years to resolve. See Staff of the Subcomm. on Health & the Environment of the House Comm. on Energy & Commerce, 99th Cong., 2d Sess., *Childhood Immunizations* 86-87 (Comm. Print 1986). Petitions in the CFC are typically resolved in two to three years, see *Statistics Report* n.1, which often includes delays sought by the claimant.

- Legal representation is readily available in the Compensation Program because it awards attorneys' fees and costs (including expert fees), even to many unsuccessful claimants. See 42 U.S.C. 300aa-15(e)(1). Under the prevailing "American Rule," the tort system offers no such inducement, even for victorious plaintiffs. See *Alyeska Pipeline Serv. Co.* v. *Wilderness Soc'y*, 421 U.S. 240, 247 (1975).

- In the Compensation Program, "informal and cooperative exchange of information is the ordinary and preferred practice," Fed. Cl. Vaccine R. 7(a), but formal discovery is available on a satisfactory showing that it is "reasonable and necessary," 42 U.S.C. 300aa-12(d)(3)(B); see Fed. Cl. Vaccine R. 7(b). Special masters have, on appro-

priate showings, permitted extensive discovery. See, *e.g.*, *Cedillo* v. *Secretary of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *9 (Fed. Cl. Feb. 12, 2009), aff'd, 89 Fed. Cl. 158 (2009), appeal pending, No. 2010-5004 (Fed. Cir. argued June 10, 2010). The government stays neutral when a claimant seeks discovery from vaccine manufacturers, leaving the claimant to face the same opponent she would in the tort system.

- Proceedings in the CFC are more flexible and less formal. For example, the formal rules of evidence do not apply, and parties may receive decisions based on written records without the burden of a trial. See 42 U.S.C. 300aa-12(d)(2); Fed. Cl. Vaccine R. 8(b)-(e).
- The burden of proof—preponderance of the evidence—is the same in both systems. And in Table injury cases, the injury is presumed to be caused by the vaccine, absent a contrary showing by the Secretary. See 42 U.S.C. 300aa-13(a)(1).
- The Compensation Program never requires proof of who manufactured the vaccine, which can be a stumbling block in the tort system, cf. *Shackil* v. *Lederle Labs.*, 561 A.2d 511 (N.J. 1989) (rejecting "market-share liability" theory advanced by plaintiff who could not identify manufacturer). Nor does the Compensation Program require proof of fault, as negligence claims do. See also *1986 Report* 13 ("[M]any vaccine-injured persons are presently without legal remedy under current tort law. * * * [M]any of these persons will be compensated for their injuries under the compensation system.").

- Substantial funds are available to pay awards under the Compensation Program, even if unexpected events place a significant demand on the Trust Fund, see *Vaccine Injury Compensation Trust Fund* 5, ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0610.pdf, and so far over $1.8 billion has been awarded, *Statistics Report* tbl. III. Awards are ample because they cover the same generally recognized special damages as the tort system, cover lost earning capacity, and include amounts for pain and suffering (subject to a cap). See 42 U.S.C. 300aa-15(a). Department of Justice records indicate that 99.8% of successful Compensation Program claimants have accepted their awards, foregoing any tort remedies against vaccine manufacturers.

b. The Act itself and the Secretary's management of the Vaccine Injury Table ensure a close fit between the Act's preemptive reach and its compensatory promise. To be included on the Table, a category of vaccine must be "recommended for routine administration to children" by CDC. 42 U.S.C. 300aa-14(e)(2) and (2)(A). Later legislation further requires that Congress act to subject the category of vaccine to the excise tax. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13632(a)(3), 107 Stat. 646. Thus, the categories of vaccines on the Table reflect the concurrent judgments of expert scientists at CDC and of Congress.

Significantly, the Table controls the Act's scope for both compensation and preemption purposes, ensuring that compensation is potentially available whenever tort remedies are preempted. The Compensation Program requires proof that the injured party received a

vaccine on the Table. See 42 U.S.C. 300aa-11(c)(1)(A), 300aa-13(a)(1)(A). And Section 22(b)(1) preempts only claims for "vaccine-related injury or death," which is by definition limited to injuries "associated with one or more of the vaccines set forth in the Vaccine Injury Table," 42 U.S.C. 300aa-33(5). Thus, in contrast to the situation in *Levine*, 129 S. Ct. at 1199, where preemption would have left the injured party without a remedy, the Act ensures that every individual injured by a covered vaccine has a complete remedy available in at least one forum.

One of petitioners' amici complains (Willner Amicus Br. 21-22, 27-31) about the Secretary's revisions to the Table. But despite the availability of citizen suits to compel changes to the Table, 42 U.S.C. 300aa-31(a), the Secretary's management of the Table has been challenged only rarely, and never successfully. New vaccines have been added to the Table without associated injuries when there was no sound evidence of such injuries. *E.g.*, 62 Fed. Reg. 7687 (1997) (*inter alia*, adding varicella vaccine with no injuries specified). New vaccines have been added with an associated injury. *E.g.*, 67 Fed. Reg. at 48,558 (*inter alia*, adding live, oral, rhesus-based rotavirus vaccines associated with intussusception). Injuries have been added for existing vaccines. *E.g.*, 62 Fed. Reg. at 7687, 7688 (*inter alia*, adding thrombocytopenic purpura for measles-containing vaccines).[8] And injuries have also been removed or mod-

[8] Significantly, amendments adding injuries or new vaccines to the Table have retroactive effect in that they allow claimants injured within eight years before the amendment—including previously unsuccessful claimants—to obtain compensation using the revised Table. See 42 U.S.C. 300aa-16(b). The tort system, of course, includes no similar exception to finality.

ified based on improved knowledge. *E.g.*, 60 Fed. Reg. 7686-7689 (1995) (*inter alia*, shortening the period for onset of anaphylaxis, modifying the definition of "encephalopathy," and removing the injury of hypotonic-hyporesponsive episode for pertussis vaccines).

This is exactly the give-and-take Congress expected. See, *e.g.*, 42 U.S.C. 300aa-14(c); Vaccine Act § 312, 100 Stat. 3779 (directing the Secretary to undertake studies of associations between certain vaccines and injuries and to make corresponding revisions to the Table). And when an injury is not listed on, or has been removed from, the Table for a listed vaccine, the Act still affords all claimants the opportunity to prove a non-Table causation claim. 42 U.S.C. 300aa-11(c)(1)(C)(ii).

3. *Congress foreclosed design-based liability because it would disserve the Act's central purposes*

Petitioners offer no sound explanation for how design-defect tort liability would be harmonious with the framework of the Vaccine Act.

a. The natural effect of holding a manufacturer liable for its product's design would be to induce it to (1) withdraw the product, (2) ameliorate the defect, or (3) pay compensation to injured users. Each of these alternatives is unavailable or would disserve the Act's central purposes.

Withdrawal of the vaccine. Without question, Congress did not want manufacturers to withdraw their vaccines from the market for fear of design-defect liability. That was exactly the crisis that precipitated the Act. See Resp. Br. 5-8.[9] Recent tragic events in California

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[9] Congress and the Secretary have since demonstrated a similar concern in responding to threats like the H1N1 influenza pandemic. See 42 U.S.C. 247d-6d (added by the Public Readiness and Emergency

are a reminder that underimmunization readily leads to the resurgence of preventable disease. See Molly Hennessy-Fiske, *California Declares Whooping Cough Epidemic*, L.A. Times, July 20, 2010, at AA1.

Withdrawal of a vaccine is particular damaging because vaccines are administered not only to immunize individuals, but also "to reduce transmission of infection and thereby to prevent disease even in non-vaccinated individuals, thus to protect communities," a phenomenon known as "herd immunity." Paul E.M. Fine & Kim Mulholland, *Community Immunity, in Vaccines* 1573. Herd immunity serves the moral imperative to protect immunologically defenseless members of society, such as the very young, the very old, and those suffering from certain diseases. Guaranteeing that a vaccine is potent enough to ensure that a disease is contained or eradicated in this way entails trade-offs between safety and potency. See *Schafer* v. *American Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994) (Breyer, C.J.); cf. *Riegel*, 552 U.S. at 325 (discussing effects of "[s]tate tort law that requires a manufacturer's [product] to be safer, but hence less effective"). The tort system—in which juries may pay little heed to this calculus, see *ibid.*—is poorly equipped to encourage such optimally safe and potent vaccines. That is why Congress recognized through the Act that expert regulators, in conjunction with the medical community, should control the availability and withdrawal of a given vaccine.

Preparedness Act, Pub. L. No. 109-146, Div. C, § 2, 119 Stat. 2818) (barring all liability for designated vaccines and other countermeasures, except for cases of "willful misconduct"); 74 Fed. Reg. 30,294 (2009) (designating H1N1 vaccine—which, unlike the trivalent seasonal influenza vaccine, is not subject to the Vaccine Act—for such protection).

Although petitioners and their amici hold up as a model Japan's experience withdrawing the DTP vaccine and turning to a DTaP vaccine, that episode was in fact the antithesis of sound public health policy. Japan began DTP vaccination in 1947; by 1974, it recorded limited pertussis cases and no deaths. Then, two infants died shortly after DTP vaccination in 1974-1975. Although investigation later established that the whole-cell pertussis component had not caused the deaths, the Ministry of Health suspended DTP vaccination, and public panic caused pertussis vaccination rates to drop to just ten percent. A pertussis epidemic ensued and led to 13,000 recorded cases and 41 deaths in 1979.[10] E.J. Gangarosa et al., *Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story*, 351 Lancet 356, 357-358 (1998); Institute of Med., *Adverse Effects of Pertussis and Rubella Vaccines* 18 (Christopher P. Howson et al. eds., 1991). That experience is a powerful illustration that "even though vaccines themselves cause a small number of serious injuries or deaths, their widespread use dramatically reduces fatalities." *Schafer*, 20 F.3d at 4. In contrast to Japan, the United States unquestionably avoided similarly extensive suffering and deaths by continuing to promote widespread DTP vaccination.

Ameliorating the defect. Design changes are not easily made to vaccines; it typically takes years of careful study with large groups to determine the safety and potency of a candidate vaccine. See p. 20, *supra*. Studies on new versions of existing vaccines are all the more difficult because medical ethics and study design considerations generally preclude testing the new vaccine on

[10] For comparison, on a population-adjusted basis, that death rate from just one disease is about the same as the rate of all serious injuries and all deaths combined caused by all vaccines subject to the Act.

a population that has enjoyed access to the proven old vaccine.

Petitioners suggest that manufacturers have "continu[ed] to sell outmoded vaccines" that "cause harm that could be avoided by another design already on the market." Br. 52, 54. It is unclear to what vaccine "already on the market" petitioners refer. See Br. 19-21. Assuming, however, that petitioners refer to Japan's early use of a DTaP vaccine (see Br. 19), they again offer an unsound model. Japan began administering a DTaP vaccine based on safety and potency studies too limited to support FDA licensing. As FDA explained at the time, the existing pertussis "vaccine is a very effective one," albeit poorly understood, and "[a]ny move to make [it] safer by modifying it is fraught with the danger of altered efficacy which cannot be adequately assessed without an extensive field trial." 50 Fed. Reg. 51,007 (1985). Moreover, trials of several candidate DTaP vaccines conducted by PHS in Sweden in 1986 were associated with serious adverse events. Jann Storsaeter et al., *Mortality and Morbidity from Invasive Bacterial Infections During a Clinical Trial of Acellular Pertussis Vaccines in Sweden*, 7 Pediatric Infectious Disease J. 637 (1988). Petitioners imply (Br. 19) that the United States was inappropriately slow to license a DTaP vaccine, but in fact the United States was the first country (after Japan) to do so. Japan took a serious public health risk, and was fortunate. But there was no quick path to improving pertussis vaccines in the United States that had the scientific rigor demanded by federal law.

Paying compensation. The Compensation Program serves the compensatory function of product liability law. See pp. 14, 25, *supra*. The Act's requirement that

vaccine-injured persons proceed first to the Compensation Program, 42 U.S.C. 300aa-11(a)(2)-(3), expresses Congress's clear intent that manufacturers not be the primary source of compensation for injuries. The Compensation Program is a "no fault" scheme analogous to other "no fault" schemes that supplant tort law. Within that framework, the vaccine excise tax that funds the Compensation Program is analogous to an insurance premium. And as with any "no fault" scheme, the Act's design is to award compensation outside the tort system.

b. These same considerations do not apply to manufacturing and labeling defects, which is why Section 22(b)(1) treats such claims differently. Unlike the sometimes unpredictable or undesirable results of changing a vaccine's design, withdrawal of a mismanufactured or mislabeled lot of vaccine is always highly desirable. Labeling defects can sometimes be corrected without discarding the vaccine, and a manufacturing defect at worst requires destruction of a particular lot. In either case, the effects on the public health are transient, if they are felt at all. Similarly, unlike changing a vaccine's fundamental design, correcting manufacturing and labeling defects is always feasible, relatively quick to implement, and independently required by law. A vaccine's biologics license reflects the manufacturing methods and labels submitted by the manufacturer. See 21 C.F.R. 601.2(a). Presumably, a manufacturer that obtains a license is readily capable of meeting the license's specifications, and indeed is required to do so by 42 U.S.C. 262(a)(1)(A).

Although the Compensation Program permits compensation for injuries from mismanufactured or mislabled vaccines, damages paid by a manufacturer are also a suitable compensation mechanism. Manufactur-

ers have thorough control over their manufacturing and labeling practices, they must adhere to the vaccine's license requirements, and they are in a clearly superior position to avoid injuries from such defects. That is far less so for injuries due to a vaccine's design, given the intense federal involvement in, and restrictions on, vaccine development and design change.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

NEAL KUMAR KATYAL
Acting Solicitor General
TONY WEST
Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
BENJAMIN J. HORWICH
Assistant to the Solicitor General
MICHAEL S. RAAB
IRENE M. SOLET
Attorneys

MARK B. CHILDRESS
Acting General Counsel
DAVID BENOR
Associate General Counsel for Public Health
EMILY MARCUS LEVINE
Senior Attorney
ANNA LORAINE JACOBS
Attorney
Department of Health and Human Services

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AMICUS CURIAE BRIEF

No. 09-152

IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD, AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF AMICI CURIAE OF THE AMERICAN ACADEMY OF PEDIATRICS AND 21 OTHER PHYSICIAN AND PUBLIC HEALTH ORGANIZATIONS IN SUPPORT OF RESPONDENT

MARK DEL MONTE
STEPHAN E. LAWTON
AMERICAN ACADEMY OF PEDIATRICS
601 Thirteenth St., N.W.
Suite 400 North
Washington, D.C. 20005

LORANE F. HEBERT
Counsel of Record
EMILY S. GEBBIA
ESTHER C. HALEY WALKER
HOGAN LOVELLS US LLP
555 Thirteenth St., N.W.
Washington, D.C. 20004
(202) 637-6536
(lorane.hebert@hoganlovells.com)
Counsel for Amici Curiae

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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BRIEF AMICI CURIAE OF THE AMERICAN ACADEMY OF PEDIATRICS AND 21 OTHER PHYSICIAN AND PUBLIC HEALTH ORGANIZATIONS IN SUPPORT OF RESPONDENT

STATEMENT OF INTEREST OF AMICI CURIAE

Founded in 1930, amicus curiae the American Academy of Pediatrics ("AAP") is a national, not-for-profit organization dedicated to furthering the interests of children's health.[1] Since AAP's inception, its

[1] Pursuant to Sup. Ct. R. 37.6, amici note that no counsel or party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the

membership has grown from 60 pediatricians to over 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 80 years, AAP has become a powerful voice for children's health through education, research, advocacy, and the provision of expert advice. AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's children to ensure the availability of safe and effective childhood vaccines, the vast majority of which are administered in pediatricians' offices after careful consultation with parents. AAP was directly involved in the drafting of the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 *et seq.*, and was a driving force behind the legislation.

Amicus curiae the AAP Section on Infectious Diseases was founded in 1990. It is comprised of AAP members who have a special interest in pediatric infectious diseases.

Amicus curiae the American Academy of Family Physicians ("AAFP"), founded in 1947 and headquartered in Leawood, Kansas, is the national association of family doctors. It is comprised of approximately 94,000 physician, resident, and student members in all 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, and the Uniformed Services of the United States. The overall mission of the AAFP is to improve the health of patients, families,

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preparation or submission of this brief. No person or entity other than amici or their members made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

and communities by serving the needs of members with professionalism and dignity.

Amicus curiae the American College of Osteopathic Pediatricians ("ACOP") is the official pediatric organization of the American Osteopathic Association. ACOP's advocacy efforts represent the interests of all U.S. osteopathic pediatricians before Congress and other governmental bodies as well as in coalition with other organizations that focus on children's welfare.

Amicus curiae the American College of Preventive Medicine ("ACPM") is the national medical society for nearly 2,500 preventive medicine physicians who are uniquely trained in both clinical and population-based medicine and who are committed to disease prevention and health promotion. Immunizations represent a major success in public health and their economic and health benefits have been well documented. ACPM believes adults and children should receive appropriately timed vaccinations that are safe and effective to protect individual and public health.

Amicus curiae the American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. Its members practice in every state

and in every field of medical specialization, including pediatrics. The AMA has long been a vocal advocate of the importance of vaccines in maintaining high standards of public health in the United States.

Founded in 1872, amicus curiae the American Public Health Association ("APHA"), is the oldest and most diverse organization of public health professionals in the world. The association aims to protect all Americans and their communities from preventable, serious health threats and strives to assure that population-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States. APHA represents a broad array of health providers, educators, environmentalists, policymakers, and health officers. APHA has a long-standing policy in support of safe and effective vaccines for children.

Amicus curiae the Association of State and Territorial Healthcare Officials ("ASTHO") is the national nonprofit organization representing the public health agencies of the United States, the U.S. Territories, and the District of Columbia, as well as the 120,000 public health professionals these agencies employ. ASTHO members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and to assuring excellence in state-based public health practice. ASTHO's vision is healthy people thriving in a nation free of preventable illness and injury.

Amicus curiae the Center for Vaccine Awareness and Research at Texas Children's Hospital in Houston was launched in 2008 to improve the health of mothers and children from infancy through adolescence by promoting and optimizing vaccine delivery

through research and through education of healthcare providers and families. The Center optimizes effective delivery of vaccinations through research, education, and advocacy, develops models to advance public health through maternal, infant, child, and adolescent immunization, and conducts vaccine research from initial feasibility studies through implementation.

Amicus curiae Every Child By Two, Carter/Bumpers Champions for Immunization ("ECBT") is a nonprofit health advocacy organization based in the United States and dedicated to protecting children from disease through promotion of vaccinations and raising parental awareness of potential vaccine benefits. ECBT was founded in 1991 by former First Lady of the United States Rosalynn Carter and former First Lady of Arkansas Betty Bumpers.

Amicus curiae the Immunization Action Coalition ("IAC") is a nonprofit organization that works to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. IAC also facilitates communication about the safety, efficacy, and use of vaccines within the broad immunization community of patients, parents, healthcare organizations, and government health agencies.

Amicus curiae the Infectious Diseases Society of America ("IDSA") represents more than 9,000 infectious disease physicians and scientists devoted to patient care, research, prevention, and public health. IDSA's purpose is to improve the health of individuals, communities, and society by promoting excel-

lence in patient care, education, research, public health, and prevention relating to infectious diseases. Its members care for patients of all ages with serious and life-threatening infections, including vaccine-preventable diseases.

Amicus curiae the March of Dimes Foundation is the leading U.S. nonprofit organization dedicated to pregnancy and the health of infants and children. Its mission is to improve the health of babies by preventing birth defects, premature birth, and infant mortality. The March of Dimes supports continuing efforts to increase immunization coverage so that children are protected from vaccine-preventable diseases to assure that diseases of the past do not return. The March of Dimes supports professional, general public, and parent education about the importance of immunizations, and also funds research into new vaccines with the potential for preventing birth defects.

Amicus curiae Meningitis Angels is a nonprofit, public advocacy organization founded in memory of Ryan Wayne Milley and dedicated to victims of bacterial meningitis and their families. Meningitis Angels educates the public, schools, daycares, colleges, the government, and the media on bacterial meningitis and its preventions, including immunizations, and promotes and sometimes conducts research on meningitis and its after-effects. Meningitis Angels works to ensure the continued availability and accessibility of immunizations to protect against vaccine-preventable diseases like bacterial meningitis.

Amicus curiae the National Association of Pediatric Nurse Practitioners ("NAPNAP") is an association of

nearly 7,500 health care providers who are committed to improving the health care of infants, children, adolescents, and young adults. NAPNAP publishes immunization materials regularly. Its Immunization Special Interest Group includes numerous experts who explore and discuss current issues of pediatric immunizations; participate at various national immunization meetings; and promote established immunization schedules and materials regarding vaccine preventable diseases and immunization practices.

Amicus curiae the National Foundation for Infectious Diseases is a nonprofit organization founded in 1973 and dedicated to providing professional and public education about the causes, prevention, and treatment of infectious diseases.

Amicus curiae the National Healthy Mothers, Healthy Babies Coalition promotes maternal and child health among a wide variety of audiences, including parents, health care professionals, and policymakers. Since its beginnings in 1981, the Coalition has promoted immunization across the lifespan as an essential strategy for optimal health. Education on this topic has been integral to the Coalition's work to ensure that every child has the best possible start and a safe and healthy environment in which to grow. The Coalition believes that it is particularly important that infants and children, those caring for them, and anyone they come in contact with be up-to-date on their immunizations so that they have full protection against vaccine-preventable diseases.

Amicus curiae the National Meningitis Association, Inc. ("NMA") is a nonprofit organization founded by

parents whose mission is to educate families, medical professionals, and others about meningococcal meningitis and prevention approaches to the disease. NMA is focused on raising awareness and protection among adolescents and young adults, many of whom can be protected through education and vaccination efforts.

Amicus curiae Parents of Kids with Infectious Diseases ("PKIDs"), a Washington nonprofit corporation, is a national association of individuals and families affected by infectious diseases, as well as healthcare professionals and others involved in disease prevention. PKIDs is the first parent nonprofit established in the United States to fight for the importance of vaccination. PKIDs was founded in 1997 to assist families affected by infectious diseases and to educate the public on various methods of disease prevention, and these remain its core purposes. PKIDs has long been a vocal advocate of the importance of vaccines in achieving high standards of public health in the United States.

Amicus curiae the Pediatric Infectious Diseases Society ("PIDS") is the world's largest organization of professionals dedicated to the treatment, control, and eradication of infectious diseases affecting children. PIDS's mission is to enhance the health of infants, children, and adolescents by promoting excellence in diagnosis, management, and understanding of infectious diseases through clinical care, education, research, and advocacy.

Founded in 1968, amicus curiae the Society for Adolescent Health and Medicine ("SAHM") is a multidisciplinary, international organization committed to improving the physical and psychosocial

health and well-being of all adolescents through advocacy, clinical care, health promotion, health service delivery, professional development, and research. The SAHM Vaccination Committee and SAHM members around the world actively work to ensure that all adolescents and young adults can access and afford recommended vaccines.

Amicus curiae the Vaccine Education Center at the Children's Hospital of Philadelphia was launched in 2000 to provide accurate, comprehensive, and up-to-date information about vaccines and the diseases they prevent to parents and healthcare professionals. The Center communicates facts about vaccines, including how vaccines are made, how and why vaccines work, who recommends them, whether they are safe, whether they are still necessary, and when they should be administered to patients.

Amici—all of whom support the routine vaccination of children against a host of vaccine-preventable infectious diseases—urge this Court to affirm the judgment of the Third Circuit below. As explained further below, Congress enacted the Vaccine Act to avert a public health crisis and thus safeguard the Nation's vaccine supply. As the Third Circuit correctly recognized, Congress achieved that objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz* v. *Wyeth Inc.*, 561 F.3d 233, 248 (3d Cir. 2009) (emphasis added).

Petitioners contend that the Act preempts design defect claims "*only* upon a threshold showing that the vaccine's side effects could not have been prevented." Pet. Br. 25 (emphasis added). That approach—which would allow judges *and juries* to

decide on a case-by-case basis whether a particular vaccine can be made safer—threatens a resurgence of "the very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act" in the first place. *Bruesewitz*, 561 F.3d at 249. This Court should accordingly reject petitioners' attempt to render Congress's action an exercise in futility.

SUMMARY OF ARGUMENT

The public health benefits of childhood vaccines cannot be overstated. Because of vaccines, a number of debilitating and life-threatening infectious diseases have been eliminated or virtually eliminated in this country, thereby not only enhancing the length and quality of life of countless children, but also providing significant savings in direct and indirect costs. It is no wonder that Congress has declared that "[t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities." H.R. Rep. No. 99-908, at 5 (1986).

In the mid-1980s, the number of vaccine-related lawsuits filed against vaccine manufacturers rose sharply. Although the tort system failed to provide adequate compensation for many children injured by vaccines, the flood of vaccine-related litigation overwhelmed vaccine manufacturers. A genuine threat to the public health emerged as manufacturers abandoned or considered abandoning the vaccine market. As the then-President of the AAP testified: "The threat to our vaccine supply in this country is a real one * * *. We could lose the remainder of our suppliers unless some positive legislative action is taken." *National Childhood Vaccine Injury Compensation Act of 1985: Hearing Before the S. Comm. on*

Labor and Human Resources, 99th Cong. 8 (Dec. 9, 1985) (hereinafter "*Dec. 9, 1985 Hearing*") (statement of Martin Smith, M.D., President of the AAP).

Congress responded by passing the Vaccine Act. The Act established a no-fault alternative compensation program intended to provide adequate compensation to children injured by vaccines and to ensure the stability of the vaccine market and thus safeguard the Nation's vaccine supply. As the Third Circuit below correctly recognized, the Act furthers that latter objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz*, 561 F.3d at 248 (emphasis added).

Petitioners contend that the Act preempts design defect claims "*only* upon a threshold showing that the vaccine's side effects could not have been prevented." Pet. Br. 25 (emphasis added). As the Third Circuit explained, however, if the Vaccine Act is interpreted "to allow case-by-case analysis of whether particular vaccine side effects are avoidable," then "*every* design defect claim is subject to evaluation by a court." *Bruesewitz*, 561 F.3d at 246 (emphasis added). Thus, adoption of petitioners' interpretation of the Act could precipitate the same crisis that Congress sought to avert in passing the Vaccine Act: "the very real possibility of vaccine shortages, and, in turn increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." H.R. Rep. No. 99-908, at 7.

ARGUMENT

I. VACCINE DEVELOPMENT IS ONE OF THE GREATEST PUBLIC HEALTH ACHIEVEMENTS OF THE TWENTIETH CENTURY.

The "[v]accination of children against deadly, disabling, but preventable infectious disease has been one of the most spectacularly effective public health initiatives this country has ever undertaken." *Id.* at 4. *See also* Centers for Disease Control and Prevention, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MMWR 241 (Apr. 2, 1999) (listing vaccination as one of the ten greatest public health achievements of the twentieth century). Indeed, "the sharp and deep reduction in [infectious] diseases * * * is [largely] attributable to the development and employment of effective vaccines." *Immunization and Preventive Medicine, 1982: Hearing Before the Subcomm. on Investigations and General Oversight of the S. Comm. on Labor and Human Resources*, 97th Cong. 103 (May 7, 1982) (hereinafter "*1982 Hearing*") (statement of Vincent A. Fulginiti, MD, Chairman, Committee on Infectious Diseases, AAP).

Because of vaccines, smallpox has been eradicated worldwide, Sandra W. Roush, *et al.*, *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 JAMA 2155, 2160 (2007), and polio, diphtheria, and tetanus have essentially been eliminated in the United States. H.R. Rep. No. 99-908, at 5. In 2007, cases of measles, mumps, rubella, and pertussis (whooping cough) were reduced by more than 90% of twentieth century baseline levels. American Academy of

Pediatrics, *Red Book: 2009 Report of the Comm. on Infectious Diseases* 2 (28th ed. 2009).

The significance of these developments is beyond dispute: "[C]hildren in the United States enjoy substantial freedom from the ravages of once common communicable infectious diseases and illnesses. These illnesses limited life expectancy and left tens of thousands disabled in their wake." *1982 Hearing*, *supra*, at 103 (statement of Vincent A. Fulginiti, MD, Chairman, Committee on Infectious Diseases, AAP). Indeed, it has been estimated that vaccination with just seven of the routinely recommended childhood vaccines "prevents an estimated 33,000 deaths and 14 million cases of disease in every birth cohort." Roush, *et al.*, *supra*, at 2160.

Notably, vaccines have achieved such success by protecting not only those who have been immunized, but others in the community who have not: "[F]or some diseases where there is person-to-person transmission, reducing the incidence by vaccination results in 'herd immunity,' with reduction of risk for all community members regardless of their individual immunization status." National Institute of Allergy and Infectious Diseases and National Institutes of Health, Task Force on Safer Childhood Vaccines, *Final Report and Recommendations* 12 (January 1998). *See also* Committee on Practice and Ambulatory Medicine and Council on Community Pediatrics, *Increasing Immunization Coverage*, 125 Pediatrics 1295, 1296 (2010) ("for most vaccine preventable diseases, achieving high levels of immunization in the community offers indirect protection to others").

Vaccines have also translated into direct savings in medical costs, as well as increased productivity from families that would otherwise be burdened by disease. Institute of Medicine, *Financing Vaccines in the 21st Century: Assuring Access and Availability* 27-29 (2004). It has been estimated that for every dollar invested in childhood vaccination against nine vaccine-preventable diseases, $5.80 is saved in direct medical costs; $17.70 is saved when indirect benefits, such as lost productivity, are taken into account. Walter A. Orenstein, *et al.*, *Immunizations in the United States: Success, Structure, and Stress*, 24 Health Affairs 599, 600 (2005). *See also* Fangjun Zhou, *et al.*, *Economic Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States, 2001*, 159 Archives of Pediatrics & Adolescent Medicine 1136, 1141 (2005) (concluding that, for the 2001 U.S. birth cohort, every dollar spent on routine childhood immunization against seven vaccine-preventable diseases resulted in a savings of more than $5 in direct costs and approximately $11 in additional costs to society). Overall, "[b]illions of medical and health-related dollars have been saved by immunizations." H.R. Rep. No. 99-908, at 4.

Of course, "[n]o vaccine is completely safe or effective." Centers for Disease Control and Prevention, *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 55 MMWR 1 (Dec. 1, 2006). *See* H.R. Rep. No. 99-908, at 6 ("There is today no 'perfect' or reaction-free childhood vaccine on the market."). Even when vaccines are properly manufactured, distributed, and administered, a small number of children may suffer rare but serious

adverse reactions. *See* H.R. Rep. No. 99-908, at 4, 6. "Despite these possibilities, public health officials, private physician groups, and parent organizations have repeatedly stated that it is safer to take the required shots than to risk the health consequences of contracting the diseases immunizations are designed to prevent." *Id.* at 6. In other words, the enormous benefits of vaccination vastly outweigh the relatively small risk of injury. *See General Recommendations on Immunization*, *supra*, at 1 ("[R]ecommendations for vaccination practices balance scientific evidence of benefits for each person and to society against the potential costs and risks for vaccination for the individual and programs."); H.R. Rep. No. 99-908, at 6 ("in light of the overall success of immunization programs, the Federal government continues to support * * * immunizations to children").

II. CONGRESS ENACTED THE VACCINE ACT TO PROVIDE ADEQUATE COMPENSATION TO CHILDREN INJURED BY VACCINES AND TO SAFEGUARD THE NATION'S VACCINE SUPPLY.

In 1986, the Nation faced a public health crisis. Vaccine-related lawsuits against vaccine manufacturers had spiked, and rising litigation and insurance costs threatened to halt vaccine production in the United States. H.R. Rep. No. 99-908, at 4, 6-7. At the same time, however, the tort system had failed to provide adequate compensation for children injured by vaccines. *Id.* at 6. Congress responded by enacting the Vaccine Act, thereby ensuring adequate compensation for children injured by vaccines and safeguarding the Nation's vaccine supply.

A. The Costs Of Vaccine-Related Litigation Had Threatened To Halt Vaccine Production In The United States.

In the mid-1980s, the number of vaccine-related suits filed against vaccine manufacturers increased markedly. *Id.* at 4. According to a 1985 survey of the seven manufacturers producing childhood vaccines,[2] between January 1980 and March 1985, 299 lawsuits were filed against them seeking compensation for vaccine-related injuries; 84 percent of those suits were related to childhood vaccines. Staff of H. Subcomm. on Health and the Environment of the Comm. on Energy and Commerce, 99th Cong., *Childhood Immunizations* 85-86 (Comm. Print 1986) (hereinafter "*Childhood Immunizations*"). About 60 percent of all the suits filed sought damages in the aggregate of $3.5 billion. *Id.* Between 1983 and 1984 alone, litigation costs nearly doubled—climbing from $4.7 million to $9.8 million. *Id.* at 87.

With the deluge of lawsuits, vaccine manufacturers faced rising insurance premiums and a decreasing pool of insurers willing to cover them. H.R. Rep. No. 99-908, at 6-7; *Childhood Immunizations*, *supra*, at 73; *National Childhood Vaccine-Injury Compensation Act: Hearing Before the S. Committee on Labor and Human Resources*, 99th Cong. 288 (July 18, 1985) (hereinafter "*July 18, 1985 Hearing*") (statement of Stephen White, Vice President of Reed-Stenhouse, Ltd.) (explaining that insurance companies were struggling with losses from pharmaceutical, asbestos, and pollution claims). As litigation and

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[2] Two of the manufacturers were operated by State organizations in Michigan and Massachusetts. H.R. Rep. No. 99-908, at 7.

insurance costs soared, "the prices of vaccines * * * jumped enormously," H.R. Rep. No. 99-908, at 4—in some cases as much as 900 percent, *see Childhood Immunizations*, *supra*, at 90—and "[t]he number of childhood vaccine manufacturers * * * declined significantly." H. Rep. No. 99-908, at 4.

As it became increasingly clear that vaccine prices could not forever keep pace with escalating litigation and insurance costs, *see, e.g.*, *July 18, 1985 Hearing*, *supra*, at 240 (statement of Robert Johnson, President of Lederle Laboratories) (noting that "vaccine pricing" of the previous year would not "cover the projected costs of liability" for the following year), the few remaining vaccine manufacturers began "to question their continued participation in the vaccine market." H.R. Rep. No. 99-908, at 7. *See July 18, 1985 Hearing*, *supra*, at 256 (statement of Robert Johnson, President of Lederle Laboratories) ("If the current trend of spiraling litigation continues or worsens, there * * * is a very real possibility that we will be forced to abandon the vaccine business."); *id.* at 284 (statement of David J. Williams, Vice President and General Manager of Connaught Laboratories, Inc.) ("There is always a possibility that Connaught will be unable to remain in the vaccine business.").

As Congress recognized, "[t]he loss of any of the existing manufacturers of childhood vaccines * * * could create a genuine public health hazard in this country." H.R. Rep. No. 99-908, at 7. At that time, "there [was] only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the [diphtheria, pertussis, and tetanus] DPT vac-

cine." *Id.*[3] Thus, as the then-President of the AAP testified: "The threat to our vaccine supply in this country is a real one * * *. We could lose the remainder of our suppliers unless some positive legislative action is taken." *Dec. 9, 1985 Hearing*, *supra*, at 8 (statement of Martin Smith, M.D., President of the AAP).

B. The Tort System Had Failed To Provide Adequate Compensation For Children Injured By Vaccines.

Ironically, while lawsuits against vaccine manufacturers skyrocketed, some children injured by vaccines failed to receive any compensation. Despite their injuries, some children were simply not deemed good "candidates for litigation," *National Childhood Vaccine-Injury Compensation Act: Hearing Before the S. Committee on Labor and Human Resources*, 98th Cong. 171 (May 3, 1984) (hereinafter "*1984 Hearing*") (statement of Andrew Dodd, Attorney at Ward, Dodd & Grant, Torrance, California), because any prospective recovery was not "large enough" to make their cases attractive to an attorney. *Id.* at 146 (statement of Martin H. Smith, M.D., President-elect of the AAP).

Thus, while a few lawsuits reaped multi-million dollar awards, some injured children received no compensation at all. 132 Cong. Rec. H30751, H30760 (Oct. 14, 1986) (statement of Rep. Waxman); *id.* at H30762 (statement of Rep. Biaggi); *1984 Hearing*, *supra*, at 4 (statement of Senator Kennedy) (tort system "awards few handsomely and sends

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[3] Michigan and Massachusetts also produced their own DPT vaccine. H.R. Rep. No. 99-908, at 7.

others equally aggrieved away penniless"). The tort system was thus aptly described as a "lottery." *1984 Hearing*, *supra*, at 277 (statement of John E. Lyons, President of Merck Sharp & Dohme).

C. The Vaccine Act Provides Adequate Compensation To Children Injured By Vaccines And Ensures The Stability Of The Vaccine Market And The Nation's Vaccine Supply.

Congress responded to the looming crisis by enacting the Vaccine Act. The overriding goals of the Act were two-fold: (1) to ensure adequate compensation for children injured by vaccines, and (2) to stabilize the vaccine market and safeguard the Nation's vaccine supply. H.R. Rep. No. 99-908, at 7.

Congress addressed both of those goals in part by establishing the National Vaccine Injury Compensation Program ("VICP"), a no-fault alternative compensation system under which children injured by certain vaccines would receive "expeditious and fair" compensation for their injuries. *Id.* at 12. *See* 42 U.S.C. § 300aa-10 *et seq.* Under the VICP, a person seeking compensation for an injury caused by a vaccine covered by the Act must file a petition with the United States Court of Federal Claims, which refers the petition to a "Vaccine Court"—an office within the court of special masters appointed to four-year terms by the court to hear VICP claims. 42 U.S.C. §§ 300aa-11(a)(1)-(2), 300aa-12(c), 300aa-21(a). The Secretary of Health and Human Services is named as a respondent; vaccine manufacturers are not parties to VICP proceedings. *Id.* § 300aa-12(b)(1).

A petitioner is entitled to compensation if he or she has suffered an injury set forth in the "Vaccine Injury Table"—a table of vaccines and the injuries presumed to be caused by those vaccines—unless it can be shown by a preponderance of the evidence that the petitioner's injury was not caused by the vaccine. *Id.* §§ 300aa-11(b), (c), 300aa-13(a)(1), 300aa-14. A petitioner who has not suffered a "Table Injury" may still obtain compensation by proving that his or her injury was in fact caused by a vaccine covered by the Act. *Id.* § 300aa-11(c)(1)(C)(ii). *See Grant* v. *Secretary of HHS*, 956 F.2d 1144, 1147-48 (Fed. Cir. 1992).[4] Payment of compensation is made

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[4] The special masters of the Vaccine Court have developed a proficiency in the complex medical and scientific issues involved in causation claims. Indeed, the Court of Federal Claims has observed that, "instead of being passive recipients of information, such as jurors, special masters are given an active role in determining the facts relevant to Vaccine Act petitions," and that "special masters have the expertise and experience to know the type of information that is most probative of a claim." *Doe* v. *Secretary, HHS*, 76 Fed. Cl. 328, 338-339 (Fed. Cl. 2007).

The expertise of the special masters in evaluating causation claims has been amply demonstrated in a multi-phase Omnibus Autism Proceeding ("OAP") established under the VICP to determine whether there is a causal link between childhood vaccines and autism. Approximately 5,000 cases alleging an association between autism and either vaccines containing the preservative thimerosal, the MMR vaccine (which does not contain thimerosal), or a combination thereof, have been filed with the Vaccine Court. *See* http://www.hrsa.gov/vaccinecompensation. In 2009, special masters in three "test" cases issued voluminous opinions evaluating evidence based on the theory that the MMR vaccine, in combination with vaccines containing thimerosal, causes autism. *See Cedillo* v. *Secretary of HHS*, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *appeal pending*, No. 2010-5004 (Fed. Cir.); *Hazlehurst* v. *Secretary of HHS*, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009),

from a "Vaccine Injury Compensation Trust Fund"—funded by a manufacturers excise tax on those vaccines covered by the Act, *see* 26 U.S.C. §§ 4131, 9510—on a no-fault basis. 42 U.S.C. §§ 300aa-13, 300aa-14, 300aa-15(i). Since 1989, the Vaccine Court has issued more than 2,400 awards totaling over $1.8 billion. *See* National Vaccine Injury Compensation Program, *Statistics Report* (June 7, 2010), *available*

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aff'd, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder* v. *Secretary of HHS*, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). All three special masters rejected the proposition that the vaccines in question caused autism. *See id.*

In reaching their decisions, the special masters in each case considered a wealth of scientific evidence. As the special master in *Snyder* observed: "The evidentiary record in this case * * * encompasses, *inter alia*, nearly four weeks of testimony, including that offered in the *Cedillo* and *Hazlehurst* cases; over 900 medical and scientific journal articles; 50 expert reports (including several reports of witnesses who did not testify); supplemental expert reports filed by both parties post-hearing, [and] the testimony of fact witnesses on behalf of [the injured child and his] medical records." *Snyder*, 2009 WL 332044, at *8. Each of the special master's decisions have been affirmed by the Court of Federal Claims; of the two cases that have been further appealed, one has been affirmed by the Federal Circuit and the other is still pending before that court. *See supra*.

In March 2010, special masters in three additional "test" cases issued voluminous opinions evaluating evidence based on the theory that thimerosal-containing vaccines alone can cause autism. *See Dwyer v. Secretary of HHS*, 2010 WL 892250 (Fed. Cl. March 12, 2010); *King v. Secretary of HHS*, 2010 WL 892296 (Fed. Cl. March 12, 2010); *Mead v. Secretary of HHS*, 2010 WL 892248 (Fed. Cl. March 12, 2010). Once again—upon consideration of a "massive" record—each of the special masters concluded that the vaccines in question did not cause autism. *King*, 2010 WL 892296, at *12. *See Dwyer*, 2010 WL 892250, at *7; *Mead*, 2010 WL 892248, at *5.

at http://www.hrsa.gov/vaccinecompensation/statistics_report.htm.[5]

After the Vaccine Court has issued a final judgment, a petitioner may accept or reject it. 42 U.S.C. § 300aa-21(a).[6] Although a party who rejects the Vaccine Court's judgment may pursue certain *limited* claims in state or federal court, design defect

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[5] Certain of petitioners' amici make much of the fact that the majority of claims filed today involve so-called "off-Table" injuries which require proof of causation. *See* Br. Marguerite Willner 22; Br. National Vaccine Information Center, *et al.* 14. Yet it would not appear that claimants have been unduly hampered by the burden of proof on causation, as amici suggest. In 2009—and to date, in 2010—compensation has been paid in over 70% of adjudicated non-autism cases. *See* National Vaccine Injury Compensation Program, *Statistics Report* (June 7, 2010). And while amici bemoan the Secretary's removal of certain injuries from the Vaccine Injury Table, *see* Br. Marguerite Willner 21-22; Br. National Vaccine Information Center, *et al.* 15-16, Congress "anticipate[d] that the research on vaccine injury and vaccine safety [then] ongoing * * * [would] soon provide more definitive information about the incidence of vaccine injury and that, when such information [were] available, the Secretary * * * [might] propose to revise the Table." H.R. Rep. No. 99-908, at 18. Thus, the Act specifically provides for the removal of injuries through notice-and-comment rulemaking. *See* 42 U.S.C. § 300aa-14(c). As contemplated by Congress, the original table was modified "to make it consistent with current medical and scientific knowledge regarding adverse events associated with certain vaccines." HHS, *National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table*, 60 Fed. Reg. 7678, 7678 (Feb. 8, 1995).

[6] The Vaccine Act also authorizes petitioners to "opt out" of a VICP proceeding if a special master has not resolved his or her petition within 240 days or if the Court of Federal Claims has not completed its review of a special master's decision within 420 days of the date on which the petition was filed. *See* 42 U.S.C. § 300aa-21(b).

claims are not among them. *Id.* § 300aa-21(a), (b). As the Third Circuit correctly held, Congress expressly preempted "*all* design defect claims, including those based in negligence." *Bruesewitz*, 561 F.3d at 248 (emphasis added). *See* 42 U.S.C. § 300aa-22(b)(1). If an injured person has such a claim, he or she "should pursue recompense in the compensation system, not the tort system." H.R. Rep. No. 99-908, at 26. The preemption of all design defect claims is critical to Congress's objective of stabilizing the vaccine market and safeguarding the Nation's vaccine supply. As the Third Circuit explained: "Congress[] belie[ved] that an alternate compensation system would reduce awards and create a stable, predictable basis for estimating liability." *Bruesewitz*, 561 F.3d at 247. Indeed, as the legislative history makes clear, Congress "believe[d] that once this system [was] in place and manufacturers ha[d] a better sense of their potential litigation obligations, a more stable childhood vaccine market [would] evolve." H.R. Rep. No. 99-908, at 7.

III. PETITIONERS' INTERPRETATION OF THE VACCINE ACT POSES A THREAT TO THE FUTURE PRODUCTION AND DEVELOPMENT OF VACCINES.

Contrary to all clear indications of congressional intent, petitioners maintain that the Vaccine Act preempts design defect claims "*only* upon a threshold showing that the vaccine's side effects could not have been prevented." Pet. Br. 25 (emphasis added). As the Third Circuit below concluded, that interpretation of the Act is simply wrong. *See Bruesewitz*, 561 F.3d at 246. As the Third Circuit explained, if the Act is interpreted "to allow case-by-case analysis of

whether particular vaccine side effects are avoidable," then "*every* design defect claim is subject to evaluation by a court." *Id.* (emphasis added).

If that were the case, "[e]ach of the objectives extolled [in the Vaccine Act's legislative history] would be undermined." *Id.* at 249. Thus, petitioners' interpretation of the statute—which allows judges *and juries* to decide whether a particular vaccine can be made safer[7]—threatens a resurgence of "the very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act" in the first place. *Id.* That threat is extremely palpable, as the recent decisions issued by the Vaccine Court in the OAP promise to unleash a barrage of claims in the courts. *See supra* at 20-21 n.4. Thus, adoption of petitioners' interpretation could drive vaccine manufacturers from the market and halt the future production and development of childhood vaccines in this country.

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[7] As this Court noted in *Riegal* v. *Medtronic, Inc.*, 552 U.S. 312, 325 (2008), with respect to medical devices, juries cannot be expected to conduct the cost-benefit analysis performed by expert regulators in balancing a device's safety and efficacy. "A jury * * * sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped the benefits are not represented in court." *Id.* That concern applies with even greater force with respect to vaccines, which benefit not only those who have been immunized but those who have not, and which thus directly benefit society at large. *See supra* at 13. In making recommendations for childhood vaccines, public officials and others have carefully "balance[d] scientific evidence of benefits for each person and to society against the potential costs and risks for vaccination for the individual and programs." *General Recommendations on Immunization*, *supra*, at 1.

A. Unpredictable Litigation Costs Could Once Again Force Vaccine Manufacturers To Abandon Or Consider Abandoning The Vaccine Market.

By eliminating the threat of most lawsuits, the Vaccine Act has prevented manufacturers from abandoning the vaccine market, thus ensuring a stable supply of vaccines. *See* Louis Z. Cooper, *et al.*, *Protecting Public Trust in Immunization*, 122 Pediatrics 149, 150 (2008). Case-by-case consideration of whether vaccines are unavoidably unsafe, on the other hand, would "undoubtedly increase the costs and risks associated with litigation and would undermine a manufacturer's efforts to estimate and control costs." *Bruesewitz*, 561 F.3d at 249. Thus, adoption of petitioners' interpretation would create the "very real possibility" that vaccine manufacturers will once again abandon or be forced to consider abandoning the vaccine market. H.R. Rep. No. 99-908, at 7.

That is particularly so given the precarious state of the vaccine industry. Today, as in 1986, there continues to be only *one* manufacturer of a measles-mumps-rubella vaccine, and only *two* manufacturers of a diptheria-tetanus-pertussis vaccine. *See* American Academy of Pediatrics, *Status of Recently Submitted, Licensed, and Recommended Vaccines, Red Book Online: Vaccine Status Table* (2010), *available at* http://aapredbook.aappublications.org/news/vaccstatus.dtl; *Childhood Immunizations*, *supra*, at 67; H.R. Rep. No. 99-908, at 7. And while the Vaccine Act has been instrumental in preventing manufacturers from fleeing the vaccine market, the number of vaccine manufacturers has not greatly increased

since the Act's passage. *See Status of Recently Submitted, Licensed, and Recommended Vaccines*, *supra*. The costs of developing and producing vaccines have also increased over the years. Between 1991 and 2003, for instance, costs for research and development, postlicensure clinical studies, and production process improvements grew from $231 million to $802 million. Stanley A. Plotkin, *et al.*, *Vaccines* 38 (5th ed. 2008).

Thus, vaccine manufacturers today are no better—and, indeed, are perhaps even more poorly—situated to handle the unpredictability and expense of litigation. Yet, as was true in 1986, "the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." H.R. Rep. No. 99-908, at 7.

B. The Progress That Has Been Made In Vaccine Development Since The Passage Of The Vaccine Act Could Come To A Halt.

In addition to ensuring the stability of the existing childhood vaccine market, one of Congress's objectives in passing the Vaccine Act was to ensure "that a greater number of vaccine products will become available to prevent disease." H.R. Rep. No. 99-908, at 4. In that regard, the Act has been unquestionably successful. Vaccine development has flourished since 1986 with the number of vaccine-preventable diseases having more than doubled. *See Childhood Immunizations*, *supra*, at 1; Centers for Disease Control and Prevention, *Recommended Immuniza-*

tion Schedules for Persons Aged 0 Through 18 Years–United States, 58 MMWR Q1-Q4 (Jan. 8, 2010).

In 1986, children were routinely vaccinated against seven diseases (diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, and tetanus). *Childhood Immunizations*, *supra*, at 1. Today, children are also routinely immunized against an additional eight diseases: *Haemophilus influenzae* type b (Hib), hepatitis A, hepatitis B, influenza, meningococcal disease, pneumococcal disease, rotavirus, and varicella (chicken pox). *Recommended Immunization Schedules for Persons Aged 0 Through 18 Years–United States*, *supra*, at Q1-Q4. Research and development of new vaccines is always ongoing. *See* Immunization Action Coalition, *Vaccine-Related Journal Articles*, *available at* http://www.immunize.org/journalarticles/ (listing, by year, published articles regarding vaccine development).

Vaccine manufacturers face many challenges in bringing new vaccines to market. *See* Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 Health Affairs 622, 623-629 (2005). In addition to research and development, vaccine manufacturers are also "almost exclusively" responsible for the production and distribution of such vaccines. *See* Orenstein, *et al.*, *supra*, at 601-603. As noted, by eliminating the threat of most lawsuits, the Vaccine Act has kept manufacturers from abandoning vaccine production. *See* Cooper, *et al.*, *supra*, at 150. If the decision below is reversed, the prognosis for future vaccine development will be extremely poor.

CONCLUSION

For the foregoing reasons, and those stated in respondent's brief, the judgment below should be affirmed.

Respectfully submitted,

MARK DEL MONTE
STEPHAN E. LAWTON
AMERICAN ACADEMY OF PEDIATRICS
601 Thirteenth St., N.W.
Suite 400 North
Washington, D.C. 20005

LORANE F. HEBERT
Counsel of Record
EMILY S. GEBBIA
ESTHER C. HALEY WALKER
HOGAN LOVELLS US LLP
555 Thirteenth St., N.W.
Washington, D.C. 20004
(202) 637-6536
(lorane.hebert@hoganlovells.com)

Counsel for Amici Curiae

AMICUS CURIAE BRIEF

No. 09-497

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ, PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ, A MINOR CHILD, AND IN THEIR OWN RIGHT,

Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, AND LADERLE LABORATORIES,

Respondents.

On Writ Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE, PUBLIC JUSTICE, AND PUBLIC CITIZEN AS AMICI CURIAE IN SUPPORT OF PETITIONERS

ANTHONY TARRICONE
AMERICAN ASSOCIATION FOR JUSTICE
777 6th St. NW, Suite 200
Washington, DC 20001
(202) 965-3500
AAJ President

Additional Counsel on Inside Cover

VALERIE M. NANNERY*
CENTER FOR CONSTITUTIONAL LITIGATION, P.C.
777 6th St. NW, Suite 520
Washington, DC 20001
(202) 944-2814
valerie.nannery@cclfirm.com
**Counsel of Record*

LESLIE BRUECKNER
PUBLIC JUSTICE, P.C.
555 12th Street, Suite 1620
Oakland, CA 94607
(510) 622-8205

Attorneys for Amici Curiae

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INTEREST OF *AMICI CURIAE*

The American Association for Justice ("AAJ"), formerly the Association of Trial Lawyers of America, Public Justice, and Public Citizen respectfully submit this brief as *amici curiae* in support of Petitioners. This brief is filed with consent of all parties.[1]

AAJ is a voluntary national bar association whose trial lawyer members primarily represent individual plaintiffs in civil suits and personal injury actions, including product liability cases and cases involving injuries caused by childhood vaccines. Throughout its history, AAJ has advocated in the courts, in Congress, and in state legislatures why it is essential to preserve the protections for ordinary citizens afforded by the common law and to ensure that state tort claims, such as product liability claims for defective design, provide injured persons with effective legal recourse and remedies for wrongful injuries. AAJ submits the lower court's decision in this case comprised an unwarranted expansion of the preemption doctrine that undermines those essential state law protections. By bringing such claims on behalf of people injured by vaccines, AAJ's members have helped to ensure that the nation's children and their families have access to safe and effective vaccines.

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[1] Letters of consent from the parties have been filed with the Clerk of Court. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored any part of this brief, nor did any person or entity other than *amici*, their members, or their counsel make a monetary contribution to its preparation or submission.

Public Justice is a national public interest law firm dedicated to pursuing justice for the victims of corporate and governmental abuses. Through involvement in precedent-setting and socially significant litigation, Public Justice seeks to ensure that tort law fully serves its dual purposes—compensating those injured by wrongful conduct and deterring similar conduct in the future. Public Justice is gravely concerned that, if the tort system is closed to innocent victims of defective childhood vaccines through application of the preemption doctrine in this case, neither of these purposes will be served.

Public Citizen, a national non-profit organization founded in 1971, works to advance consumers' interests on a broad range of issues. For example, through its Health Research Group, Public Citizen engages in research, education, and advocacy with respect to the safety of products regulated by the Food and Drug Administration (FDA). Where FDA regulation is insufficient to protect consumers against the consequences of unsafe medical products, Public Citizen supports injured patients' right to seek redress. In that regard, Public Citizen believes that, absent an express congressional determination to the contrary, states should remain free to compensate tort plaintiffs as they deem appropriate. With this principle in mind, Public Citizen, through its Litigation Group, has represented plaintiffs in several significant preemption cases involving FDA-regulated products. *See, e.g.*, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

SUMMARY OF ARGUMENT

This Court has long recognized the importance of providing a remedy to those injured by wrongful conduct. Access to common law tort remedies ensures confidence in our system of government. While recognizing Congress' authority to preempt state law, the Court sees Congressional abolition of state common law claims as rare, and requires that Congress be *clear* when it preempts state common law.

The court below erred in holding that the National Childhood Vaccine Injury Act ("NCVIA" or "Vaccine Act") expressly preempts ***all*** design defect claims against vaccine manufacturers under state product liability law. In so doing, the Third Circuit gave little weight to the presumption against preemption. Instead of identifying a "clear and manifest" purpose of Congress to preempt ***all*** design defect claims, the Third Circuit looked at the imagined consequences of ***not*** barring all such claims in order to piece together its determination that Congress could not have intended such consequences and so must have intended to preempt such claims. If the scope of the Vaccine Act's preemption provision cannot be resolved from the statutory text alone, as the Third Circuit itself said, the Third Circuit's reliance on policy arguments to infer Congressional intent effectively disregards the strong presumption against preemption and is unpersuasive even on its own terms.

The Third Circuit's interpretive choice turns the preemption provision of the Vaccine Act into an absolute immunity law and, for those injured by childhood vaccines, removes an important choice that

Congress intended to preserve—the choice to seek a common law remedy in court. Immunizing vaccine manufacturers from *all* state law claims for defective design would undermine one of the purposes of the federal regulation of vaccines and of tort liability—to make vaccines safer.

There was good reason for Congress to keep state tort law available to those injured by childhood vaccines. This country's civil justice system not only provides compensation to those injured by defective products, but also ensures that safer vaccines are made available by encouraging manufacturers to develop and seek licenses for better, safer vaccines. The state tort law system sheds light on previously unknown hazards, and allows discovery of information that is distinctly within the knowledge of vaccine manufacturers. Congress did not intend to dispose of the public health and safety benefits provided by the state tort law system.

ARGUMENT

I. RECOGNIZING THE IMPORTANCE OF REMEDYING INJURIES, THIS COURT HAS NOTED THAT CONGRESSIONAL ABOLITION OF STATE LAW CLAIMS IS RARE.

This Court has for more than two centuries held that "[o]ne of the first duties of government" is to safeguard "the right of every individual to claim the protection of the laws, whenever he receives an injury." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803). Under the Due Process Clause of the Fourteenth Amendment, it is "the duty of every State to provide, in the administration of justice, for the

redress of private wrongs." *Missouri Pac. Ry. Co. v. Humes*, 115 U.S. 512, 521 (1885). Indeed, the right to recover damages for wrongful personal injury is among the "absolute rights of individuals" that the Founders intended to guarantee to all Americans. *See Ingraham v. Wright*, 430 U.S. 651, 661, 672-74 (1977).

Preservation of access to the courts for all is essential to promoting public confidence in and respect for our legal system, without which our courts cannot operate. The civil justice system provides the best opportunity for an average person to achieve redress of injuries against wrongdoers, regardless of wealth and rank. The political or economic advantages that unfairly favor powerful industries and the wealthy in the legislative arena do not matter in a courtroom. In American courtrooms, decisions are made according to the rule of law, not political or economic influence. *See Marbury v. Madison*, at 163 (this is a "government of law, and not of men."). *Cf. Chisholm v. Georgia*, 2 U.S. (2 Dall.) 419, 479 (1793) (The civil justice system "leaves not even the most obscure and friendless citizen without means of obtaining justice. . . . [I]t recognizes and strongly rests on this great moral truth, that justice is the same whether due from one man or a million, or from a million to one man; because it teaches and greatly appreciates the value of our free republican national Government, which places all our citizens on an equal footing, and enables each and every one of them to obtain justice without any danger of being overborne by the weight and number of their opponents."). The importance of the civil liability system weighs against federal preemption of state common law, except in rare circumstances.

While this Court has recognized Congress' authority to preempt state tort laws entirely, it has also recognized that Congress *rarely* expressly preempts state tort law. *See, e.g., Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7 (2003); *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69-70 (2002); *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449-50 (2005); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 868 (2000). The court considers such sweeping preemption "unusually 'powerful,'" *Beneficial Nat'l Bank*, 539 U.S. at 7, and thus requires Congress to be very clear in expressly preempting state tort law. *See Medtronic, Inc., v. Lohr*, 518 U.S. 470, 487 (1996) (plurality opinion). For Congress to have eliminated that right for those injured by unreasonably dangerous vaccines, without specifically saying so, would have been "spectacularly odd." *Medtronic, Inc.*, 518 U.S. at 491 (1996).

II. THE THIRD CIRCUIT FAILED TO APPLY THE STRONG PRESUMPTION AGAINST PREEMPTION OF STATE LAW REMEDIES FOR PERSONAL INJURY.

One of two cornerstones of this Court's canons of construction regarding preemption provisions is the presumption against preemption. In *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), this Court reaffirmed that the presumption against preemption applies "in all pre-emption cases" and can be overcome only by a showing of "clear and manifest" purpose to preempt. *Id.* at 1194-95. The presumption applies "[w]hen addressing questions of express or implied pre-emption." *Altria Group, Inc. v. Good*, 129 S. Ct. 538,

543 (2008); *see also Medtronic, Inc.*, 518 U.S. at 485. Under this presumption, the Court assumes "that the historic police powers of the State [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Altria Group, Inc.*, 129 S. Ct. at 543 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). *See also Bates*, 544 U.S. at 449 ("In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'"); *Cipollone*, 505 U.S. at 516.

The presumption against preemption is particularly strong where Congress preempts in a field of traditional state regulation. *Altria Group, Inc.*, 129 S. Ct. at 543; *Medtronic, Inc.*, 518 U.S. at 485. As this Court has acknowledged repeatedly, "regulation of health and safety matters is primarily, and historically, a matter of local concern," within the police powers of the States. *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985).

Issues of health and safety have traditionally fallen within the province of state regulation, *see, e.g., Medtronic, Inc.*, 518 U.S. at 485. States have a powerful interest in regulating vaccination within their borders to protect the health of their citizens, and thus have an interest in providing a remedy when their citizens are injured by vaccines and do not receive adequate compensation from the National Vaccine Injury Compensation Program. When those injured by vaccines are not compensated or are inadequately compensated for their avoidable injuries, the States often bear the burden of providing financial and medical assistance to the

vaccine-injured and their families. Although the safety and availability of vaccines is also an area of federal interest, "'[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" *Levine*, 129 S. Ct. at 1200 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989)).

Here, Congress enacted the Vaccine Act to divert claims from the tort system for potential resolution in an administrative regime in order both to reduce the costs of litigation to those injured by vaccines and to provide injured victims compensation. However, because Congress understood that the traditional tort system "provide[s] important incentives for the safe manufacture and distribution of vaccines," *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, J.), it did not immunize manufacturers from suit. The Vaccine Act expressly permits tort suits if the injured party is unsatisfied with the award she receives, or if the administrative system fails to provide an award or judgment within a reasonable time. *See* 42 U.S.C. §§ 300aa-21, 300aa-11(a)(2)(A). Moreover, Congress expressly preempted state law that would prevent a vaccine-injured person from bringing suits not expressly barred by the Vaccine Act. In sum, Congress legislated against a backdrop where tort liability was available to those injured by vaccines, understood tort liability to be important for vaccine safety, and envisioned tort suits being available after the vaccine-injured exhaust their administrative remedies under the Vaccine Act.

Despite the presumption against preemption, the text of the Vaccine Act, and Congress' awareness of the operation of state law in this area, the Third Circuit found that Congress clearly and manifestly intended to bar all design defect claims against vaccine manufacturers. The Third Circuit paid lip service to the presumption against preemption, but failed to give it its proper weight. The Third Circuit defended its approach on the ground that interpreting the Vaccine Act to only preempt design defect cases in *some* cases—i.e., when an injury or death is "unavoidable"—would require case-by-case determinations by courts on whether the injury was avoidable or not. The lower court held that Congress *could not* have intended all design defect claims to be evaluated by the courts despite the absence of express language or evidence showing a *clear and manifest purpose* to preempt all design defect claims against vaccine manufacturers.

The Third Circuit also confused state law determinations that state substantive law of products liability bars certain design defect claims with Congressional intent to preempt. *Bruesewitz v. Wyeth*, 561 F.3d 233, 246 (3d Cir. 2009) (noting that in 1986, when Congress enacted the Vaccine Act, *some* courts had barred *some* design defect claims against *prescription drug manufacturers* under state law, and concluding that Congress "could not have intended" to allow even different design defect claims to go forward against vaccine manufacturers in those states). These state law determinations are particular to each state, and are not evidence of *Congress' purpose* in enacting the Vaccine Act.

The Third Circuit's attempt to cobble together some reason Congress would want to bar *all* design

defect claims against vaccine manufacturers flies in the face of this Court's repeated admonitions that only a "clear and manifest" Congressional purpose may overcome the presumption against preemption. The Third Circuit's approach effectively turns the presumption on its head to one that clearly *favors* preemption.

III. TRADITIONAL STATE TORT LAW COMPLEMENTS THE PURPOSES OF THE VACCINE ACT BY ENHANCING AND ENSURING THE SAFETY OF CHILDHOOD VACCINES.

The Third Circuit was incorrect when it held that allowing any design defect claims against vaccine manufacturers would undermine the objective of ensuring vaccine development and availability. *Bruesewitz*, 561 F.3d at 248-49. In so ruling, the lower court failed to recognize the value of the state tort law system, a recognition that Congress respected in designing the Vaccine Act, and failed to recognize that state tort law and federal regulation are complementary systems that can comfortably co-exist. The Third Circuit gave little heed to this Court's instruction to approach the question of federal preemption of state law with "the general understanding of common-law damages actions" and their role in product safety. *Cipollone*, 505 U.S. at 521.

The Vaccine Act created an administrative remedial system "that tries more quickly to deliver compensation to victims, while also reducing insurance and litigation costs to manufacturers." *Schafer*, 20 F.3d at 2. Indeed, it allows manufacturers to avoid or defer most litigation costs

because the manufacturers do not participate in the Vaccine Program proceedings at all. *See* 42 U.S.C. § 300aa-12(b) (the Secretary of Health and Human Services is the respondent in all proceedings); Vaccine R. of the U.S. Ct. of Fed. Claims 15 (no third parties may intervene, but "interested individuals" may "submit relevant written information"). The compensation and attorneys' fees provided by the Vaccine Act come from a fund created by Congress from appropriations in the first few years after enactment of the Vaccine Act, and afterward by an excise tax on each dose of vaccine. *See* 42 U.S.C. § 300aa-15(i); 26 U.S.C. §§ 4131, 9510.

While the Vaccine Act increased reporting requirements for vaccine manufacturers and health care providers, 42 U.S.C. § 300aa-25(b), and gave authority to the Secretary of Health and Human Services to promote the development and improvement of childhood vaccines, 42 U.S.C. § 300aa-27, the Vaccine Act does not contain any provisions that would directly encourage or require vaccine manufacturers, who generate profit from the distribution of childhood vaccines, to improve their own products. Thus, there is nothing in the Vaccine Act itself that requires a vaccine manufacturer with a license for a vaccine that was developed fifty years ago to research and develop a safer, cost-competitive alternate design.

The tort system, however, provides precisely this impetus to manufacturers. Congress recognized this fact, and accordingly rejected bills that would have immunized manufacturers from product liability claims. *See* H.R. 5184, 99th Cong. § 2122(c)(1) (1986); *National Childhood Vaccine Injury Compensation Act of 1985 (Part 2): Hearing on S.827*

Before the S. Comm. On Labor & Human Resources, 99th Cong. 16 (1985). It would be unwise for this Court now to deny this important tool to those who suffer avoidable injuries from childhood vaccines. Tort liability enhances the safety of products, particularly those that are as ubiquitous as childhood vaccines.

A. Product Liability Law Plays a Distinct and Important Role in Protecting Public Safety.

Mass production and mass marketing of consumer products have brought great progress and prosperity to Americans over the past century. Indeed, mass vaccination programs have led to healthier children and communities, and long life-expectancy for all Americans. *See, e.g.*, H.R. Rep. No. 99-908, at 4 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. But unreasonably dangerous products also pose grave risks of personal injury and death. Thus, the United States has depended upon a two-pronged approach to ensuring product safety.

Governmental regulation assumes that the marketplace cannot achieve the desired level of safety and instead imposes safety by decree. Product liability, on the other hand, operates indirectly through the marketplace. By requiring the manufacturer to internalize the costs of injury as part of the price of the product, the market creates a financial incentive for manufacturers to make their products reasonably safe.

Product liability is an adaptation of the common-law fault principle to the modern

marketplace, beginning with Justice Cardozo's landmark decision in *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916), more fully developed in *Greenman v. Yuba Power Products*, 377 P.2d 897 (Cal. 1963), and reaching its most widely adopted formulation in Restatement (Second) of Torts § 402A (1965). *See generally*, Gary T. Schwartz, *The Vitality of Negligence and the Ethics of Strict Liability*, 15 Ga. L. Rev. 963 (1980). While tort law has been called "law with a human face," Peter H. Schuck, *Introduction: The Context of the Controversy* 17, 21, *Tort Law and the Public Interest* (Peter H. Schuck ed., 1991), with its primary purpose being compensation of those who have been wrongfully injured, tort law claims for product liability also play an indirect role providing market incentives for safety. *See* John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 826 (1973).

It is well-accepted that in a marketplace in which all actors have perfect knowledge of risks, the market itself would provide the most efficient allocation of resources to produce reasonably safe products. Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & Econ. 1 (1960); Jon D. Hanson & Kyle D. Logue, *The First-Party Insurance Externality: an Economic Justification for Enterprise Liability*, 76 Cornell L Rev. 129, 161 (1990) (noting that the Coase Theorem is "well accepted"). That is, the market would favor products with the lowest sum of the cost of injuries plus the cost of injury prevention.

Of course, real-world markets do not provide perfect consumer information. And manufacturers are able to "externalize" the injury costs of their products. Guido Calabresi, *The Costs of Accidents*

144-45 (1970). That is, the manufacturer can force consumers, taxpayers, and society generally to subsidize its products by bearing part of the cost of the injuries they cause. This places the manufacturer who invests in safety at a competitive disadvantage. Product liability rules, by assessing risk retrospectively, compensate for imperfect consumer information. Steven P. Croley & Jon D. Hanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 Mich. L. Rev. 683, 707-08 (1993). *See also* W. Kip Viscusi, *Reforming Products Liability* 66 (1991) ("The purpose of products liability is to fill the gaps left by market imperfections and to replicate the incentives that would have been generated had markets been functioning perfectly.").

In this way, product liability lawsuits "promot[e] optimal deterrence—the taking of precautions and selection of activities that minimize the sum of accident costs and accident avoidance costs." Kenneth S. Abraham, *The Insurance Effects of Regulation by Litigation, in Regulation Through Litigation*, 212, 232 (W. Kip Viscusi ed. 2002). It is for the manufacturer to decide rationally whether it is cheaper to prevent future injuries by investing in safety precautions or simply to compensate future victims. *Id.*

Product liability duties therefore reflect a policy of making dangerous products pay their own way, that is, internalizing costs to achieve an efficient level of manufacturing operations. William M. Landes & Richard A. Posner, *The Positive Economic Theory of Tort Law*, 15 Ga. L. Rev. 851, 871-77 (1980); Richard C. Ausness, *Compensation For Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 36 Wayne L. Rev. 1085, 1140

(1990) ("efficient allocation of resources is more likely if product prices reflect their actual social costs").

Viewed another way, the law requires the product's purchase price to reflect the costs of injuries so the "cheapest cost avoider" makes the most efficient allocation of resources. Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 Yale L.J. 1055, 1060 (1972) ("The question for the court reduces to a search for the cheapest cost avoider," i.e., which of the parties to the accident is in the best position to make the cost-benefit analysis between accident costs and accident avoidance costs and to act on that decision once it is made.); *see also* Stephen G. Breyer, *Administration and Its Reform* 175 (1982) (favoring rule "likely to place costs on the party best able to avoid them").

To the extent that preventing injury is cheaper than compensating the injured, tort liability provides manufacturers with an economic incentive to make their products safer. *Id.* In this way, tort liability "is broadly consistent with an optimum investment in accident prevention by the enterprises subject to the standard." Richard A. Posner, *A Theory of Negligence*, 1 J. Legal Stud. 29, 30 (1972).

Simply the *prospect* of product liability claims, without any actual liability, can deter negligent behavior and can drive product manufacturers to make safety improvements long before regulation or the market alone could force such developments. *See* John D. Graham, *Product Liability and Motor Vehicle Safety, in The Liability Maze: The Impact of Liability Law on Safety and Innovation* 120, 180-81 (Peter W. Huber & Robert E. Litan eds., 1991). The

fear of unwanted publicity of product liability suits, too, regardless of any actual liability, can be a catalyst for safety improvements. *Id.* at 181-82. *See* Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 U.C.L.A. L. Rev. 377, 409, 415-16 (1994) (discussing risk managers' assessments of the impact of tort liability on their own safety efforts).

Safety by government regulation is a much different regime. It is premised on the belief that the marketplace cannot achieve the level of safety society demands. Croley & Hansen, *supra* at 736. In many ways, regulation and tort liability are polar opposites. Administrative regulations are prospective; tort liability assesses past conduct. Regulations may mandate specific design or performance standards; a jury verdict assesses whether a manufacturer met a duty of care. Regulatory penalties can be imposed to enforce compliance; a liability verdict is measured to compensate for wrongful death and injury. *See generally*, Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. Legal Stud. 357 (1984).

In his classic exposition, Judge Calabresi contrasts the indirect influence exerted on the market by tort law ("general deterrence") with governmental regulatory mandates ("specific deterrence"). Calabresi, *The Costs of Accidents*, *supra*, at 68-129. As one scholar summarized: "[U]nder a *general deterrence* regime, manufacturers, not government officials, make decisions about product safety." Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 Syracuse L. Rev. 897, 927 (1988) (emphasis added).

For this reason, this Court has consistently held that even where a federal agency has authority to oversee regulation of a particular national concern, state tort liability is not inconsistent with federal authority. *See, e.g.*, *Wyeth v. Levine*, 129 S. Ct. at 1200-04; *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988). *See also English v. General Elec. Co.*, 496 U.S. 72, 85 (1990) (the effect of tort awards "is neither direct nor substantial enough to place petitioner's claim in the pre-empted field" with administrative regulations); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 258 (1984) (vesting federal agency "with exclusive regulatory authority over the safety aspects of nuclear development" was not inconsistent with allowing plaintiffs to recover for injuries caused by nuclear hazards).

In addition, "tort law often informs regulatory decisions, and the FDA has often acted in response to information that has come to light in state damages litigation." David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warm Claims*, 96 Geo. L.J. 461, 477 (2007-2008) (citing *Bates*, 544 U.S. at 451); *see also* Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings & Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218 (2002). The "legal system [has] played an important role in spurring change in regulatory or corporate procedures, as well as extending knowledge about drug risks by adding to the evidence available for evaluation by physicians, patients, and regulators." Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 310 (2007).

In all of these ways state product liability law plays an important role in ensuring the safety of consumer products.

B. The Third Circuit's Holding That the Vaccine Act Bars *all* Design Defect Claims Undermines the Goal of Vaccine Safety.

It is well understood that imposing liability on manufacturers for their defective products will encourage the development of safer products because it

> discourages others from similar tortious behavior, fosters safer products . . . , vindicates reasonable conduct that has regard for the safety of others, and, ultimately, shifts the risk of loss and associated costs of dangerous activities to those who should be and are best able to bear them.

Shackil v. Lederle Labs., 561 A.2d 511, 537 (N.J. 1989) (O'Hern, J., dissenting). The Third Circuit's holding fails to explain how the Vaccine Act promotes the discovery and development of safer vaccines if manufacturers are given a "blanket tort immunity for design defects." *Am. Home Prods. v. Ferrari*, 668 S.E. 2d 236, 242-43 (Ga. 2008).

Within the Vaccine Program, vaccine manufacturers are not held directly liable for anything. Even if the Special Master determines that a child was injured by a vaccine that could have been safer, i.e., a vaccine suffering from a design defect, the manufacturer of that vaccine never has to internalize the cost of its defective design. The Fund

pays compensation to the injured parties, and deterrence is lost. The Vaccine Program itself provides no incentive to vaccine manufacturers to make their vaccines safer.

"Rather than working at odds with each other, federal regulation and state common law acting in concert can improve vaccine safety of existing vaccines and spur the development of improved vaccines." *Mazur v. Merck & Co.*, 742 F. Supp. 239, 248 (E.D. Pa. 1990), *aff'd on other grounds*, 964 F.2d 1348 (3d Cir. 1992). *See also MacGillivray v. Lederle Labs. Div. of Am. Cyanamid Co.*, 667 F. Supp. 743, 745 (D.N.M. 1987) ("[F]ederal regulations are designed to assure the manufacture and distribution of effective, safe pharmaceutical products for the consumer. A tort judgment against a drug manufacturer may in fact accelerate the development of better, safer products."). Tort actions may lead manufacturers to seek approval of safer alternatives to the vaccines for which they already have licenses, or lead the National Vaccine Advisory Committee to call for the development of new vaccines or the refinement of current vaccines. Discovery may bring new information to light that spurs agency action to ensure the safety of vaccines, or leads regulators to reassess their prior safety determinations. As the former FDA Chief Counsel has written, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 11 (1997). *See also* 1 American Law Institute, *Reporters' Study: Enterprise Responsibility For Personal Injury* 50 (1991); Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J.

Legal Stud. 357 (1984); Susan Rose-Ackerman, *Tort Law in the Regulatory State, in Tort Law and the Public Interest* 80, 82-83 (Peter H. Schuck ed., 1991).

The specter of damage actions may provide the manufacturers themselves with added dynamic incentives to improve their products and develop new ones. The goal of vaccine safety "is more enhanced than frustrated by state law." *Abbot by Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1113 (4th Cir. 1988).

> [B]y allowing a tort action . . . to proceed the national goal of optimum vaccine safety is actually enhanced. While Congress intends vaccines to be at least as uniformly safe as the FDA regulations require, there has never been a congressional intent that innocent victims of adverse reactions should be precluded from being compensated or from demonstrating that the vaccines could be even safer thereby encouraging additional efforts on the part of the vaccine manufacturers.

Graham v. Wyeth Labs., 666 F. Supp. 1483, 1493 (D. Kan. 1987), *aff'd in part, rev'd on other grounds*, 906 F.2d 1399 (10th Cir. 1990). In passing the Vaccine Act, Congress recognized that immunizing an entire industry from tort claims and thus shifting financial responsibility for the injuries caused by its products to others could destroy incentives to make vaccines safer. *Schafer*, 20 F.3d at 3. By barring *all* design defect claims, the Third Circuit crippled the efforts of *everyone* concerned with vaccine safety, not just those who were injured by avoidably unsafe vaccines.

C. The Availability of State Tort Law Claims for Design Defects Against Vaccine Manufacturers Will Not Harm the Safety or Availability of Vaccines.

This is not the first time that a vaccine manufacturer has sought immunity from design defect claims. Prior to the enactment of the Vaccine Act, vaccine manufacturers sought refuge under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Public Health Service Act ("PHSA"), 42 U.S.C. §§ 247b and 262. *See, e.g., Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1988); *Abbot* 844 F.2d at 1112 n.1; *Mazur*, 742 F. Supp. at 239; *Foyle v. Lederle Labs.*, 674 F. Supp. 530, 534 (E.D.N.C. 1987); *Martinkovic v. Wyeth Labs., Inc.*, 669 F. Supp. 212, 215 (N.D. Ill. 1987); *MacGillivray*, 667 F. Supp. at 746 n.1; *Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1340 (C.D. Cal. 1987); *Graham*, 666 F. Supp. at 1492; *Patten v. Lederle Labs.*, 655 F. Supp. 745, 749 (D. Utah 1987); *Wack v. Lederle Labs.*, 666 F. Supp. 123, 127-28 (N.D. Ohio 1987).

Vaccine manufacturers have consistently argued that common law tort actions interfere with federal determinations regarding the safety of vaccines, impose a heavy cost on manufacturers resulting in price increases for vaccines, and have the potential to lead to withdrawal of manufacturers from the vaccine market. *See, e.g., Hurley*, 863 F.2d at 1177; *Abbot*, 844 F.2d at 1113. Yet faced with these claims from the manufacturers, the courts that have addressed the purported conflict between federal regulation of vaccines and state common law liability for unsafe products consistently refused to

give vaccine manufacturers the immunity from suit that they sought. *Hurley*, 863 F.2d at 1177, 1178 ("Moreover, it is not clear that the cost of compensating children injured by the vaccine would drive manufacturers from the business; the manufacturers may be able to raise prices and preserve their profit margins. Because the vaccine price is paid by the federal government, this would make the vaccination program a greater burden on the public fisc, but it would not discourage parents from having their children vaccinated."); *Abbot*, 844 F.2d at 1113; *Mazur*, 742 F. Supp. at 246-47; *Foyle*, 674 F. Supp. at 534; *Martinkovic*, 669 F. Supp. at 215; *MacGillivray*, 667 F. Supp. at 746 n.1; *Morris*, 667 F. Supp. at 1340; *Graham*, 666 F. Supp. at 1492; *Patten*, 655 F. Supp. at 749; *Wack*, 666 F. Supp. at 127-28.

Vaccine manufacturers' doomsday claims are not new. Respondents and their *amici* raise the same policy arguments that were made more than 20 years ago, prior to the Vaccine Act's enactment—i.e., that safety is ensured by FDA approval of vaccines and that civil juries are poorly equipped to judge the safety of vaccines. *See* Brief of United States as Amicus Curiae at 14-15 *Am. Home Prods. Corp. v. Ferrari*, 129 S. Ct. 2786 (Mem.) (2009) (No. 08-1120), 2010 WL 342143. These arguments were rejected under the FDCA and PHSA, and the Vaccine Act does not change the analysis.

While the intervention of the Vaccine Act added a new remedial scheme and modified some tort law, the Vaccine Act did not change the way vaccine safety is regulated by the FDA. The FDA still only considers the safety and effectiveness of the vaccines submitted to it by the manufacturers, and

cannot force manufacturers to seek approval for safer, alternative designs. *See* 21 U.S.C. §§ 301-393. While the Vaccine Act added reporting requirements and gave the Secretary of Health and Human Services authority to promote research and development of safer vaccines, it did not change the passive nature of FDA regulation of vaccines. *See* 42 U.S.C. §§ 300aa-25-28. Thus, under the Vaccine Act, state tort claims for design defect *still* complement the federal regulation of vaccines and do not frustrate federal law objectives in the regulation of vaccines.

The arguments favoring preemption of all state law design defect claims fail to recognize that state tort law enhances the safety of vaccines by giving manufacturers incentive to make safer vaccines. Those arguments also fail to recognize that even without complete immunity from design defect claims, the Vaccine Act significantly reduces insurance and litigation costs to vaccine manufacturers through other means, and that abolishing tort law claims for defective design would threaten the public health.

1. The Vaccine Act provides adequate protection to the stability of the vaccine market even without providing absolute immunity from suit for design defects.

Under the Vaccine Act, a person injured by a vaccine administered after October 1, 1988, is effectively prohibited from filing a civil action until *after* his or her claim under the Act has been adjudicated in the Vaccine Program. 42 U.S.C. §

300aa-11(a). The party can file suit at that time only if it waives any compensation awarded under the Act. 42 U.S.C. § 300aa-21. Within the Program, vaccine manufacturers are not party to the proceedings, and thus bear no litigation costs unless and until the injured person exhausts her administrative remedy. 42 U.S.C. § 300aa-12(b). Even if an injured person proves that the vaccine that caused her injury was defectively designed, and is awarded compensation, the vaccine manufacturer is not directly liable for the award.

By requiring claimants to exhaust their administrative remedies in the Program prior to filing a court action, Congress hoped to divert a significant number of litigants, and thus save manufacturers a great sum in litigation costs. It is only after this administrative remedy proves unfruitful or unsatisfactory that the manufacturers ever are called to account for their defective products in a court of law. The purpose of the system is to *reduce* litigation, but not entirely preempt state laws. *See Abbot*, 844 F.2d at 1117 (Wilkins, J., concurring).

Given the differences in state products liability law, many common law actions are difficult to win. This makes it unlikely that many vaccine-injured claimants will risk an award of compensation from the Vaccine Program to pursue a tort action, and makes it even less likely that claimants who are unsuccessful under the Vaccine Program will be successful under state common law. *See, e.g. Schafer*, 20 F.3d at 6.

Even if a vaccine-injured person pursues a tort action alleging design defect, manufacturers have additional protections built into the Vaccine Act:

Congress prohibited tort awards for "unavoidable" injuries from vaccines, 42 U.S.C. § 300aa-22(b), abolished any obligation of manufacturers to provide direct warnings to those injured by vaccines or their legal representatives, 42 U.S.C. § 300aa-22(c), imposed a presumption that vaccines contained adequate warnings if the manufacturer complied with federal regulations, 42 U.S.C. § 300aa-22(b)(2) and eliminated punitive damages in most cases, 42 U.S.C. § 300aa-23. *See Schafer*, 20 F.3d at 3. All of these measures aim to reduce the burden of tort litigation on vaccine manufacturers. But the manufacturers and their *amici* now claim that these protections are not enough, and seek from this Court what they were unable to gain from Congress in the Vaccine Act: complete immunity from *all* design defect claims.

The manufacturers' assertions that allowing claims like the Petitioners' to go forward will result in catastrophic results is hyperbole, at best. Just as the courts that addressed similar claims by vaccine manufacturers recognized in the 1980s, the state tort law system is complementary to the purposes of federal law, and there is good reason to allow such claims to be evaluated by the courts.

2. The absence of State tort liability for defective vaccines would lead to more severe consequences than those the vaccine manufacturers predict would result from the availability of such claims.

Contrary to Respondents' claims, it is the *absence* of state tort liability for design defects that

would harm public safety by both reducing incentives for vaccine manufacturers to make safer vaccines and by discouraging vaccine use by increasing fears about vaccine safety. Extinguishing tort liability for defective design would also force consumers and the States to bear the cost of any avoidable injury caused by vaccination that is not compensated (or is inadequately compensated) by the Vaccine Program.

Most states require children to be vaccinated in order to attend public school, and most children must be vaccinated in order to attend private school or participate in most of the recreational sports and activities that many children enjoy. While the States have a strong interest in having children vaccinated, they also have a strong interest in providing a remedy for children who are injured by vaccines and who elect a state tort law remedy rather than an award by the Vaccine Program. Furthermore, the States have an interest in "encouraging drug manufacturers to provide the safest possible vaccines," *see Graham*, 666 F. Supp. at 1493 n.5, otherwise the States themselves may have to bear the costs of those who suffer avoidable injures from vaccines. If a vaccine-injured individual and her family do not have the resources to cover the costs of her avoidable injury, state public assistance programs, hospitals and other state resources may be forced to pay for these costs.

With regard to mandatory vaccination, parents do not have any *real* choice as to whether their children receive the vaccines that they do. Even if parents are properly warned of the actual risks of a particular vaccine, they can hardly be said to freely accept the risk of horrible injuries that result in rare cases. It is one thing to proffer a

medicine to a prospective user and tell them that the drug that can save them from a debilitating disease has serious side effects, and then allow the consumer to choose. It is something else to require parents to vaccinate their children and also require them to carry the entire burden when their children suffer a serious side effect caused by the vaccine and when the Vaccine Program fails to provide them adequate compensation.

In these circumstances, the marketplace and federal regulation are inadequate to protect individuals *or* the States. If there is only one vaccine available on the market because the manufacturer only sought approval for that vaccine, market forces and federal regulation cannot make that vaccine safer. Consumers do not have a choice of a safer vaccine, and they *must* inoculate in order to participate in other areas of daily life. The federal regulators cannot force the manufacturer to apply for a license for a different, safer vaccine. And if a person injured by that vaccine is uncompensated or unsatisfied with the compensation provided by the Vaccine Program, the Third Circuit's interpretation of the Vaccine Act leaves the States and the individuals themselves to bear the costs of those avoidable injuries.

"A state may decide that while it must abide by the FDA's determination that a drug is marketable, the manufacturer must nonetheless bear the expense of the risk of injuries, particularly where there is evidence that suggests that the product may be subject to improvement." *MacGillivray*, 667 F. Supp. at 745-46. Abolishing state tort law claims for design defects might lead the States to reassess and change their vaccination

requirements. Parents might lobby for such a change or simply refuse to vaccinate their children, choosing to bear the cost of a potential illness rather than a debilitating life-long condition. Either of these outcomes would degrade the public health.

CONCLUSION

For the foregoing reasons, *amici curiae* the American Association for Justice, Public Justice, and Public Citizen urge this Court to reverse the judgment of the United States Court of Appeals for the Third Circuit.

Respectfully Submitted,

Valerie M. Nannery
Counsel of Record
CENTER FOR CONSTITUTIONAL LITIGATION, P.C.
777 6th Street NW, Suite 520
Washington, DC 20001-3723
202 / 944-2814

June 1, 2010

No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ,
PARENTS AND NATURAL GUARDIANS OF HANNAH BRUESEWITZ,
A MINOR CHILD, AND IN THEIR OWN RIGHT,

Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES,
WYETH-AYERST LABORATORIES, WYETH LEDERLE,
WYETH LEDERLE VACCINES, AND LADERLE LABORATORIES,

Respondents.

On Writ Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE, PUBLIC JUSTICE, AND PUBLIC CITIZEN AS AMICI CURIAE IN SUPPORT OF PETITIONERS

CERTIFICATE OF COMPLIANCE

As required by Supreme Court Rule 33.1(h), I certify that the Brief of the American Association of Justice, Public Justice, and Public Citizen as *Amici Curiae* in Support of Petitioners contains 6,921 words, excluding the parts of the document that are exempted by Supreme Court Rule 33.1(d).

I declare under penalty of perjury that the foregoing is true and correct.

June 1, 2010.

Valerie M. Nannery
CENTER FOR CONSTITUTIONAL LITIGATION, P.C.
777 6th Street, NW
Suite 520
Washington, DC 20001-3723
202 / 944-2814
* *Counsel of Record*

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CERTIFICATE OF SERVICE

I, Valerie Nannery, a member of the Bar of this Court, hereby certify that on this 1st day of June, 2010, three copies of the Brief of the American Association of Justice, Public Justice, and Public Citizen as *Amici Curiae* in Support of Petitioners in the above-entitled case were served via Federal Express for overnight delivery, to each counsel listed below. I further certify that all parties required to be served have been served.

David C. Frederick
Counsel of Record
Derek T. Ho
Brendan J. Crimmins
Janie N. Kucera
Kellogg, Huber, Hansen, Todd, Evans & Figel, P.L.L.C.
1615 M Street, NW
Suite 400
Washington, DC 20036
202 / 326-7900
dfrederick@khhte.com

John Eddie Williams
John T. Boundas
Williams, Kherkher, Hart, Boundas, LLP
8441 Gulf Freeway
Suite 600
Houston, TX 77017
713 / 230-2200

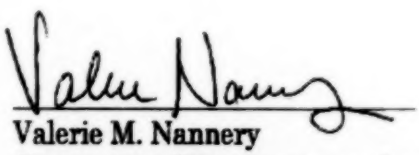
Collyn A. Peddie
Law Offices of Collyn Peddie
440 Louisiana Street
Suite 1710
Houston, TX 77002
713 / 422-1205
cp@collynpeddie.com

Counsel for Petitioners

Kathleen M. Sullivan
Counsel of Record
Faith E. Gay
Sanford I. Weisburst
Quinn, Emanuel, Urquhart & Sullivan, LLP
51 Madison Avenue
22nd Floor
New York, NY 10010
212 / 849-7000
kathleensullivan@quinnemanuel.com

Daniel J. Thomasch
Richard W. Mark
E. Joshua Rosenkranz
Lauren J. Elliott
John L. Ewald
Orrick, Herrington & Sutcliffe
666 Fifth Avenue
New York, NY 10103
212 / 506-5000
dthomasch@orrick.com

Counsel for Respondents



Valerie M. Nannery
CENTER FOR CONSTITUTIONAL LITIGATION, P.C.
777 6th Street, NW
Suite 520
Washington, DC 20001-3723
202 / 944-2814

AMICUS CURIAE BRIEF

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IN THE
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Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF *AMICI CURIAE* PATRICIA A. BUFFLER, DIEGO T. BURIOT, JOSE CORDERO, RONALD E. GOTS, RONALD HART, STEVEN H. LAMM, ANGUS NICOLL, ONORA O'NEILL, SAMUEL OSHER, JAMES D. WATSON AND RICHARD WILSON IN SUPPORT OF RESPONDENT

MARTIN S. KAUFMAN*
* *Counsel of Record*
Atlantic Legal Foundation
2039 Palmer Avenue
Larchmont, New York 10538
(914) 834-3322
Counsel for Amici Curiae

July 30, 2010

QUESTION PRESENTED

Does Section 22(b)(1) preempt vaccine design-defect claims categorically, or must a vaccine manufacturer also show, case by case, that the side effects at issue could not have been avoided by some differently designed vaccine?

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INTEREST OF *AMICI*

Amici are scientists who are deeply interested in this case and its impact on the quality of healthcare, particularly the broad availability of affordable and effective preventative measures, specifically vaccines, at reasonable cost. *Amici*'s concerns are informed by decades of experience and accomplishment in their respective fields of scientific endeavor. They submit this brief to emphasize the critical role played by vaccination in fostering public health.[1]

Patricia A. Buffler is Professor of Epidemiology at the School of Public Health of the University of California at Berkeley, and is Dean *emerita* of the School of Public Health of the University of California at Berkeley. Among many honors and activities in the field of epidemiology, Dr. Buffler is a Fellow of the American College of Epidemiology, and was President of that organization in 1991-1992. She is a member of the Institute of Medicine of the National Academy of Sciences and a Fellow of the American Association for the Advancement of Science.

Diego T. Buriot, M.D., M.P.H., is a consultant in international health. He is presently World Health Organization ("WHO")-Pan American Health Organization Special Advisor for Haiti. Over the past

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[1] Pursuant to Rule 37, the parties have consented to the filing of this brief; their letters of consent are on file with the Clerk of the Court. In accordance with Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. *Amici* submit this brief in their individual capacities; the views expressed are not those of the institutions with which they are affiliated.

twenty years he has held several WHO senior positions and provided leadership expertise and negotiation skills in a wide variety of situations both at global and country levels. He established and led, as Director, the WHO Communicable Disease Surveillance (CSR) Office in Lyon, France, dedicated to the strengthening of epidemiology and laboratory capacities in developing countries. Dr. Buriot was, until 2006, Special Advisor to the WHO and he worked on issues related to bio-security, emerging infections, research on communicable diseases, and on issues related to complex emergencies. Dr. Buriot is a graduate of the University of Paris (M.D.) and Harvard University (M.P.H.). He is Board Certified in Pediatrics and Infectious Diseases. He began his career as Assistant Professor of Paediatrics in Paris and subsequently worked at the Centers for Disease Control and Prevention on the Combating Childhood Communicable Disease Project. He has worked extensively in Africa, the Middle East and the Commonwealth of Independent States (CIS) (former Soviet Union countries) to develop and review national communicable diseases control programs. He served in an advisory capacity to several international organizations, including the World Federation of Scientists and United Nations Economic, Scientific and Cultural Organization. Dr Buriot is the author of over 50 original publications, reviews, and book chapters on global health issues.

Jose Cordero, M.D., M.P.H. is Dean of the University of Puerto Rico Graduate School of Public Health. Prior to his appointment as Dean, Dr. Cordero was an Assistant Surgeon General of the United States Public Health Service. In 1994, Dr. Cordero was appointed deputy director of the National Immunization Program, where he made important and long-lasting

contributions in many areas of one of the nation's most successful public health programs. He was the founding Director of the National Center on Birth Defects and Developmental Disabilities ("NCBDDD") at the Centers for Disease Control and Prevention ("CDC") in Atlanta, Georgia. He served in that capacity since the establishment of the NCBDDD, was created by the Children's Health Act of 2000. NCBDDD is a leading international institution devoted to research and prevention of birth defects and developmental disabilities and health promotion of people of ages living with disabilities. Dr. Cordero worked for 27 years at the CDC and has extensive public health experience in the fields of birth defects, developmental disabilities, and child health. Dr. Cordero's work has been published in many national and international journals.

Ronald E. Gots, M.D., Ph.D. specializes in toxicology and environmental medicine. He is Principal of the International Center for Toxicology and Medicine and Medical Director and President of the National Medical Advisory Service. He is Adjunct Professor of Pharmacology at Georgetown University School of Medicine. He has been Coordinator of the Pharmaceutical Class Labeling Project of the U.S. Food and Drug Administration, Medical Director and Examining Physician of the Occupational Health Units, Bureau of Economic Analysis, Census Bureau and Immigration and Naturalization Service, Senior Investigator/Chief in the Department of Gastroenterology, Walter Reed Army Institute of Research.

Ronald Hart is Director Emeritus of the National Center for Toxicological Research. He was a Distinguished Scientist in Residence, United States Food and Drug Administration. Dr. Hart was Adjunct Professor of Cancer Prevention at the Strang Cancer Research Institute of Rockefeller University and Professor in the Department of Radiology at Ohio State University. He also was Chairman of the United States Interagency Committee on Environmental Health and Related Topics and was a principal author of the Technology Transfer Act, 1986. Dr. Hart developed the first direct proof that DNA damage was a cause of cancer (1974), established much of the modern basis for the role of food intake on aging, degenerative disease occurrence and chaired the White House Consensus Policy on Chemical Carcinogenesis.

Steven H. Lamm, M.D., D.T.P.H. is a medical doctor and holds a diploma in tropical public health and a master of science degree in biophysics. He is board certified in pediatrics, occupational medicine, and preventive medicine. He is a charter fellow of the American College of Epidemiology, and a winner of the Annual Prize of the Society for epidemiologic research. Dr. Lamm is on the attending faculties of the Johns Hopkins University-Bloomberg School of Public Health (Health Policy and Management) and the Georgetown University Department of Pediatrics (Epidemiology). He has conducted studies on vaccine safety for thirty years, including studies in the United States, Europe (Poland), and South America (Amazon). He is Clinical Assistant Professor of Pediatrics at Georgetown University School of Medicine. He was Senior Epidemiologist in the Epidemiology Branch of the National Institute of Child Health and Human Development of the National Institutes of Health; he

was also an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention.

Angus Nicoll is head of the Influenza Program of the European Centre for Disease Prevention and Control. ("ECDC") and is a Professor at the London School of Hygiene and Tropical Medicine.

Onora O'Neill CBE, FBA, F. Med. Sci., Hon. FRS is a Harvard trained philosopher whose work focuses on ethics and political philosophy, including medical and research ethics. She was Principal of Newnham College, Cambridge University from 1992 to 2006, is professor *emerita* in the Faculty of Philosophy in Cambridge University, and was President of the British Academy from 2005 to 2009. She is an independent (non-party) peer in the U.K. House of Lords (Baroness O'Neill of Bengarve). She is a past chair of the Nuffield Council on Bioethics, and has served on House of Lords Select Committees dealing with Stem Cell Research, Genomic Medicine, Nanotechnology and Food and Behavioural Modification, and is a Trustee of several U.K. charities that work to improve public understanding of science, including the Nuffield Foundation (chair); Sense About Science; and the PHG Foundation.

Samuel Osher, M.D. is a physician with the Harvard University Health Service, and Clinical Instructor in Medicine at the Harvard Medical School. His clinical interests include preventive care and hypertension.

James D. Watson is a Nobel Laureate in Medicine (1962) (with F.H.C. Crick and M.H.F. Wilkins), and co-discoverer of the structure of DNA. Dr. Watson has also been awarded the John Collins Warren Prize of the Massachusetts General Hospital, the Albert Lasker

Prize of the Public Health Association, the John J. Carty Gold Medal of the National Academy of Sciences, and the Presidential Medal of Freedom. He earned his Ph.D. in Zoology, and has been awarded numerous honorary degrees. He was director and president of the Cold Spring Harbor Laboratory of the National Institutes of Health, and is currently Chancellor *emeritus* of the Cold Spring Harbor Laboratory.

Richard Wilson is Mallinckrodt Research Professor of Physics *emeritus* at Harvard University and immediate past Director of the Regional Center for Global Environmental Change at Harvard University. He is an Affiliate of the Center for Science and International Affairs and the Center for Middle Eastern Studies at Harvard University. Professor Wilson is a past Chairman of the Harvard University Department of Physics. He is a founder of the Society for Risk Analysis. Professor Wilson has been a consultant to the United States government and foreign governments on toxicology, epidemiology, public health and safety, nuclear safety, and risk assessment. Professor Wilson's areas of expertise include elementary particle physics, radiation physics, chemical carcinogens, air pollution, ground water pollution, and human rights. He is the author of more than 880 published papers on subjects including carcinogenic risk, statistical distributions of health risks, cancer risk management, public health, environmental pollution, and risk benefit analysis, including RICHARD WILSON & EDMUND A. C. CROUCH, RISK-BENEFIT ANALYSIS (2nd ed. 2001).

STATEMENT

Both the briefs by the petitioner and the respondent in this case emphasize the issue of whether federal law preempts state law, but they say little about the public health and scientific issues which the law should, and in this case does, address. These public health and scientific issues are fundamental in many ways. It is important that the scientific and public health considerations that underlie that intent be fully considered. The Court will no doubt wish to divine the intent of Congress in enacting the relevant legislation.

Mankind constantly faces the issue of how to balance the rights of an individual and the role of society and its institutions. It is vital to emphasize, and to consider especially carefully, the situations where the motives, the risks, and the rewards are different. Vaccination is one of these issues.

A. The Importance of Vaccination

Vaccines are among the most effective tools available for preventing infectious diseases and their complications and sequelae.[2]

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[2] "Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. REP. NO. 99-908, pt. 1, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 ("1986 House Report"). For example, between 1934 and 1984, diphtheria, tetanus and pertussis ("DTP") vaccines helped reduce reported cases of pertussis by 99%. J. Bass & S. Stephenson, *The Return of Pertussis*, 6 PEDIATRIC INFECT. DIS. J. 141 (1987).

There can be no doubt of the fantastic success of vaccination since it was first introduced over two centuries ago, and became standard and widespread, and in many instances mandatory, more than a century ago. Primarily because of the availability of vaccines to protect against many infectious diseases, most of us will no longer die from infectious disease but from other causes. Indeed, in one case, smallpox, the disease was eradicated in the last half century, except for a handful of laboratory samples.

High immunization coverage has resulted in drastic declines in vaccine-preventable diseases, particularly in many high- and middle-income countries. Vaccination is one of the greatest public health achievements in the United States during the twentieth century. A reduction in the incidence of a vaccine-preventable disease often leads to the public perception that the severity of the disease and susceptibility to it have decreased. S.B. Omer et al., *Vaccine Refusal, Mandatory Immunizations, and the Risks of Vaccine-Preventable Diseases*, 360 NEW ENG. J. MED. 1981 (2009); *see also* R. Chen & B. Hibbs, *Vaccine Safety: Current and Future Challenges*, 27 PEDIATR. ANNALS 445 (1998). Immunizations have eradicated smallpox world-wide; have eliminated poliomyelitis in the Americas; and have controlled measles, rubella, tetanus, diphtheria, Haemophilus influenzae type b (Hib), and other infectious diseases. We know that vaccines have dramatically reduced the number of people who get infectious diseases. Without vaccines, epidemics of vaccine-preventable diseases would return, resulting in increased and unnecessary illness, disability, and death. History shows that in times of high vaccine coverage and very low incidence of vaccine-preventable diseases, it is common and very easy to shift attention

away from the real benefits of vaccines to potential vaccine risks. *Vaccines: Finding the Balance Between Public Safety and Personal Choice: Hearing Before the H. Comm. on Govt. Reform*, 106th Cong. 84 (Aug. 3, 1999) (hereinafter "*Hearing*") (statement of David Satcher, M.D., Ph.D., Assistant Sec'y for Health and Surgeon General) *available at* http://www.hhs.gov/asl/testify/t990803a.html (last visited July 29, 2010).

Vaccines which protect against disease by inducing immunity are widely and routinely administered around the world based on the common sense principle that it is better to keep people from falling ill than to treat them once they are ill. Suffering, disability, and death are avoided. Immunization has million of deaths each year. World Health Organization, *Immunization Against Diseases of Public Health Importance* (Mar. 2005), available at http://www.who.int/mediacentre/factsheets/fs288/en/index.html (last visited July 29, 2010). Contagion is reduced, strain on healthcare systems is eased, and money is frequently saved and can be used for other health or other public services.

An immunization campaign carried out by the World Health Organization (WHO) from 1967 to 1977 eradicated the natural occurrence of smallpox. When the program began, the disease still threatened 60% of the world's population and killed every fourth victim. Eradication of poliomyelitis is within reach. Since the launch by WHO and its partners of the Global Polio Eradication Initiative in 1988, infections have fallen by 99%, and some five million people have escaped paralysis. Between 1999 and 2003, measles deaths dropped worldwide by almost 40%, and some regions

have set a target of eliminating the disease. Maternal and neonatal tetanus will soon be eliminated in 14 of 57 high-risk countries. *See* World Health Organization, *Immunization Against Diseases of Public Health Importance* (2005), *available at* http://www.who.int/mediacentre/factsheets/fs288/en/index.html (last visited July 29, 2010).

Routine vaccination is now provided in all developing countries against measles, polio, diphtheria, tetanus, pertussis, and tuberculosis. To this basic package of vaccines, which served as the standard for years, have come new additions. Immunization against hepatitis B is now recommended by WHO for all nations, and currently is offered to infants in 147 of 192 WHO Member States. Immunization against Haemophilus influenzae type b is recommended where resources permit its use and the burden of disease is established; it is provided in 89 countries (only in selected parts of two of those countries). Yellow fever vaccine is offered in about two-thirds of the nations at risk for yellow fever outbreaks. Routine immunization against rubella is provided in 111 countries. In industrialized countries a wider span of protection is typically provided than in developing countries, often including vaccines against influenza, predominant strains of pneumococcal disease, and mumps (usually in combination with measles and rubella vaccine). World Health Organization, *Immunization Against Diseases of Public Health Importance*, *supra*.

In the United States vaccination programs have eliminated or significantly reduced many diseases. However, these diseases still exist and can once again become common, and deadly, if vaccination coverage does not continue at high levels. Vaccine-preventable

diseases have many social and economic costs: for example, sick children miss school and parents may have to take time off from work; these diseases also result in doctor visits, hospitalizations, and even premature deaths. *See* Centers for Disease Control and Prevention, *What Would Happen If We Stopped Vaccinations?* (July 7, 2010), available at http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm (last accessed 07-29-2010).

Immunization is considered among the most cost-effective health investments.[3] There is a well-defined target group; contact with the health system is only needed at the time of delivery; and vaccination does not require any major change of lifestyle.

B. The Societal Interest In Vaccination

Thus, there is a strong societal interest in encouraging widespread vaccination, an interest that can best be fostered on a national level. A decision to vaccinate is a decision to help protect not only individuals, but also to protect entire communities from

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[3] In the mid-1990s, vaccines to provide "basic" coverage for tuberculosis, polio, diphtheria, tetanus, pertussis, and measles cost about $1.00 per child. Inclusion of vaccines for hepatitis B and Hib raises the vaccine cost to $7.00 to $13.00 per child (not including administration and injection equipment) in the developing world. When vaccine administration is included, the costs amount to between $20.00 and $40.00 per child. *See* World Health Organization, *Immunization Against Diseases of Public Health Importance* (2005), http://www.who.int/mediacentre/factsheets/fs288/en/index.html (last visited July 29, 2010). In addition to the health benefits to individuals and the community, "Billions of medical and health-related dollars have been saved by immunizations." H.R. Rep. No. 99-908, at 4.

diseases spread by person-to-person transmission. A decision to not vaccinate puts the individual and the community at risk. When immunization programs achieve high levels of "community" immunity or what scientists sometimes refer to as "herd" immunity (the indirect protection of a community, including unvaccinated individuals), the likelihood that an infected person will transmit the disease to a susceptible individual is greatly reduced. Community immunity provides indirect protection to children who may be too young for certain vaccinations or have other health problems that prevent them from being immunized, yet are still susceptible to the disease. For example, children under one year old are too young to receive the measles vaccine but receive some protection from the vaccination of older individuals. Children who cannot be vaccinated with some vaccines for medical reasons such as childhood leukemia are also protected. *See Hearing, supra.* These groups are often more susceptible to the complications of infectious diseases than the general population of children and depend on the protection provided by the vaccination of children in their environs. *See* K.A. Poehling et al., *Invasive pneumococcal disease among infants before and after introduction of pneumococcal conjugate vaccine,* 295 JAMA 1668-74 (2006).

As Surgeon General David Satcher stated at a Congressional Hearing in 1999, "Protecting our society from debilitating and deadly diseases that can be prevented through the administration of vaccines is a cornerstone for ensuring the health and well-being of our citizens. Vaccines are highly effective in preventing death and disability, and save billions of dollars in health costs annually." *See Hearing, supra.*

C. The Unavoidable Risks of Vaccines

Notwithstanding the enormous benefits of vaccines, experts recognize that "[n]o vaccine is completely safe or effective." Centers for Disease Control and Prevention, *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 55 MORBIDITY AND MORTALITY WEEKLY REP. 1 (2006) *available at* www.cdc.gov/mmwr/pdf/rr/rr5515.pdf (last visited July, 29, 2010)

Even when vaccines are properly manufactured and administered, a small number of children may suffer serious adverse reactions. *See See* H.R. REP. NO. 99-908 at 4, 6. Despite these risks, public health officials and physicians' organizations have consistently advised that it is safer to take the required inoculations than to risk the health consequences of contracting the diseases immunizations are designed to prevent and "in light of the overall success of immunization programs, the Federal government continues to support . . . immunizations to children." *Id.* at 6. The benefits of vaccination clearly outweigh the comparatively small risk of injury.

SUMMARY OF ARGUMENT

The public health benefits of childhood vaccines cannot be overstated. Because of vaccines, a number of debilitating and life-threatening infectious diseases have been eliminated or virtually eliminated in this country, the length and quality of life of countless children has also been increased and significant savings in direct and indirect costs have been realized. Thus, the finding of Congress that "[t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities," H.R. REP. NO. 99-908 at 5 (1986), was fully justified.

In passing the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1, *et seq.* (The "Vaccine Act" or the "Act"), Congress was responding to a concern that fear of enormous exposure to tort liability would significantly reduce the availability of essential vaccines. Congress was also mindful of the need to provide for fair and efficient compensation for those who were injured by vaccines.

The Vaccine Act established a no-fault alternative compensation program intended to provide adequate compensation to children injured by vaccines and to ensure the stability of the vaccine market and thus safeguard the Nation's vaccine supply. As the Third Circuit correctly recognized, the Vaccine Act furthers that vital objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 248 (3rd Cir. 2010) (emphasis added).

ARGUMENT

PREEMPTION OF STATE COURT ACTIONS BASED ON DESIGN DEFECT CLAIMS IS ESSENTIAL TO EFFECT THE INTENT OF CONGRESS IN ENACTING THE VACCINE ACT

Mankind clearly needs to, and for the most part wants to, continue and expand vaccination. The motive for society is clear – to develop "herd immunity." However, since an individual can obtain much of the advantage of the "herd immunity" without being vaccinated, so long the neighbors are, and since every vaccine has side effects (hopefully affecting only a small number of people, largely at random) there is a small incentive for an individual not to be vaccinated, although the un-vaccinated individual remains at some risk.

Public health experts and authorities recommended a no-fault compensation program to compensate anyone who suffered these side effects and thereby to reduce the incentive for an individual to refuse vaccination. Recognizing this, Congress, in 1986, passed the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1, *et seq.*

A. The Objectives of the Vaccine Act

"[T]wo overriding concerns" prompted passage of the Vaccine Act: "the inadequacy -- from both the perspective of vaccine-injured persons as well as vaccine manufacturers -- of [a tort law] approach to compensating those who have been damaged by a vaccine," and "the instability and unpredictability of the childhood vaccine market," due to vaccine

manufacturers' inclination to leave the market out of fear of potentially enormous tort liability. H.R. REP. NO. 908, at 7.[4]

The Vaccine Act thus had two goals. One goal was to ensure the continued supply of essential childhood vaccines by reducing the burden of litigation that had driven a number of vaccine manufacturers from the market, threatening the nation's vaccine supply. A second goal was to provide a streamlined and liberal administrative compensation scheme for those children who suffer from the rare side effects of some vaccines. Thus, the Act is designed to encourage "development and distribution of vaccines that will further enhance the public health" and to compensate individuals injured by such vaccines. H.R. REP. NO. 908, at 7.

B. The Compensation Scheme

Congress addressed the need for adequate and efficient compensation by establishing the National Vaccine Injury Compensation Program ("VICP") as an alternative to personal injury lawsuits, under which children injured by certain vaccines would receive "fair and expeditious" compensation for their injuries. *Id.* at 12; 42 U.S.C. §§ 300aa-10, *et seq.*

A person seeking compensation for an injury caused by a vaccine covered by the Vaccine Act must file a

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[4] "The number of childhood vaccine manufacturers [had] declined significantly," H.R. REP. NO. 99-908, at 4, while those that remained "question[ed] their continued participation in the vaccine market." This "unstable and unpredictable childhood vaccine market," *id.* at 5, led to "a short term crisis of availability of DTP vaccine." *Id.*, at 7.

petition with the Court of Federal Claims ("CFC"), which refers the petition to the an office of special masters appointed to hear vaccine injury claims (known as "Vaccine Court"). 42 U.S.C. §§ 300aa-11(a)(1)-(2), 300aa-12(c), 300aa-21(a). The Secretary of Health and Human Services is the respondent and vaccine manufacturers are not parties to the proceedings. *Id.*, § 300aa-12(b)(1). The award of the Vaccine Court is reviewable by the CFC and by the U.S. Court of Appeals for the Federal Circuit. 42 U.S.C. § 300aa-12(c)-(f).

A claimant is entitled to compensation if he or she has suffered an injury set forth in the "Vaccine Injury Table" (a "Table injury"), unless it can be shown by a preponderance of the evidence that the injury was not caused by the vaccine. *Id.* §§ 300aa-11(b), (c), 300aa-13(a)(1), 300aa-14.[5, 6]

Awards cover medical costs, lost earning capacity, and pain and suffering. 42 U.S.C. § 300aa-15(a). To ensure that claimants can afford legal representation, the VCIP allows recovery of reasonable attorneys' fees even if there is no award to the claimant if the claim was brought in good faith and on a reasonable basis. 42 U.S.C. 300aa-15(e). Awards are paid from a "Vaccine Injury Compensation Trust Fund" funded by an excise tax on the manufacture of vaccines covered by the Act.

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[5] The Vaccine Injury Table is a list of vaccines and the injuries presumed to be caused by those vaccines. (*See* 42 C.F.R. § 100.3)

[6] A claimant who has not suffered a "Table Injury" may still obtain compensation by proving that his or her injury was in fact caused by a vaccine covered by the Act. 42 U.S.C. § 300aa-21(a).

26 U.S.C. § 4131 (imposing an excise tax on certain types of vaccines); *id.* § 9510 (creating a trust fund)

After the Vaccine Court has issued a final judgment, a petitioner may accept or reject it. 42 U.S.C. § 300aa-21(a).[7] If the claimant rejects the CFC's judgment the claimant may bring a civil action against the manufacturer, 42 U.S.C. §§ 300aa-11(a)(2)(A), 300aa-21(a)-(b); such actions is governed by state law, subject to the Vaccine Act's limitations. 42 U.S.C. § 300aa-22.

The criteria for accepting a claim are important.[8] The adequacy of compensation is important. The criteria should, and probably will, change with time. However, this is not an issue before the Court in this case.

C. The Preemption Provision

An important element for ensuring the continued and affordable supply of vital vaccines is the preemption provision of the Vaccine Act, 42 U.S.C. § 300aa-22(b)(1), which provides that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death," except "as provided in subsections (b), (c) and (e) of this section." 42 U.S.C. § 300aa-22(a), 22(b)(1).

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[7] A claimant may withdraw a petition if the special master or the CFC fails to render a judgment within specified time limits.

[8] In the case at hand, *amici* know of no good evidence that DPT vaccines cause seizures and do not question the judgment of the Vaccine Court on this issue.

Section 22(b)(1) establishes limits on state law civil tort liability. The provision bars state law tort liability against manufacturers of childhood vaccines for all claims except for those based on manufacturing defects and failures to warn:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1).

The Third Circuit correctly recognized that the Vaccine Act furthers that vital objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 248 (3rd Cir. 2010) (emphasis added). Section 300aa-22(b)(1) bars state law tort liability of manufacturers of childhood vaccines for all possible claims except manufacturing defect and failure to warn claims.

Vaccine preparation and labeling are subject to approval by the Food and Drug Administration ("FDA") and it would be absurd if the uniform national standards were replaced by individual state procedures and approvals. While we must acknowledge that FDA's procedures can never be perfect, and constant improvements are to be sought, with expected reduction of side effects, it would defeat the purpose of the national policy to encourage development and production of vaccines for a manufacturer to be liable

even if the manufacturer complied with FDA approved procedures.[9]

An interpretation of the Vaccine Act that would allow design-defect claims to be asserted in state tort litigation would frustrate Congress's purpose. Vaccine and immunization policy involve complex decisions balancing safety and effectiveness. Jury trials in 50 jurisdictions would likely produce inconsistent decisions about whether a vaccine design is defective and thus the basis for substantial exposure to damages. Even a few jury verdicts finding a design defect could quite possibly result in withdrawal of that vaccine from the market.

National public health policy decisions should not be made in state court litigation over whether a vaccine was manufactured according to its FDA approved design, or whether a manufacturer has complied with applicable regulations and provided FDA with all required information before and after a vaccine's licensure so as to enjoy presumptive protection from failure to warn claims under 42 U.S.C. § 300aa-22(b)(2).[10]

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[9] More logical perhaps, but in the view of *amici* still not sensible, would be to hold a physician liable if he fails to choose the "best" of all vaccines approved by the FDA.

[10] Federal versus state jurisdiction has important public health implications which have changed over time. The states have traditionally had the authority to take forceful (even draconian) action in the interests of public health and safety. *See, e.g., Jacobson v. Massachusetts*, 197 U.S. 11 (1905), in which the Court endorsed the rights of states to pass and enforce compulsory vaccination laws and which served as the foundation for many state public health laws; *see also Zucht v. King*, 260 U.S.

(continued...)

CONCLUSION

In making the decision in this case, *amici* urge the Court to be mindful of the importance of vaccination to individual health and to the public good by ensuring that there is an adequate supply of vaccines available at reasonable cost and the importance of a uniform national policy encouraging the availability of safe and effective vaccines.

The decision of the Court of Appeals should be affirmed.

July 30, 2010

Respectfully submitted,

MARTIN S. KAUFMAN*
* *Counsel of Record*
Atlantic Legal Foundation
2039 Palmer Avenue
Larchmont, New York 10538
(914) 834-3322
mskaufman@atlanticlegal.org
Counsel for Amici Curiae

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[10](...continued)
174 (1922), in which the Court, deciding a case filed by a girl excluded from a public school (and later a private school) found school immunization requirements to be constitutional. Courts have been generally supportive of the states' power to enact and implement immunization requirements. Increasing interstate and international travel has made the federal role increasingly relevant and important. At the time of the SARS epidemic in China, for example, travelers from China were questioned, and in future situations travelers are likely to be checked for fever with simple thermometry. This would be far harder to do at every state border if it were not conducted at the port of entry.

AMICUS CURIAE BRIEF

No. 09-152

In the Supreme Court of the United States

RUSSELL BRUESEWITZ, *et al.*,

Petitioners,

v.

WYETH, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

ROBIN S. CONRAD
AMAR D. SARWAL
National Chamber Litigation Center, Inc.
1615 H Street, N.W.
Washington, DC 20062
(202) 463-5337

DAVID M. GOSSETT
Counsel of Record
BRIAN J. WONG
Mayer Brown LLP
1999 K Street, NW
Washington, DC 20006
(202) 263-3000
dgossett@mayerbrown.com

Counsel for Amicus Curiae

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT[1]

INTEREST OF THE *AMICUS CURIAE*

The Chamber of Commerce of the United States of America (Chamber) is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the nation's business community.

This is one such case. The Chamber—which has filed amicus briefs in prior preemption cases, including *Wyeth* v. *Levine*, 129 S. Ct. 1187 (2009), *Altria Group, Inc.* v. *Good*, 129 S. Ct. 538 (2008), *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008), *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861 (2000), and *United States* v. *Locke*, 529 U.S. 89 (2000)—is well-situated to address the issue of preemption raised here. Its members, which include manufacturers that depend

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[1] Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored this brief in whole or in part and that no party, counsel for a party, or any person other than *amicus* and its counsel made a monetary contribution intended to fund the preparation or submission of the brief. The parties have lodged letters with the Clerk expressing their blanket consent to the filing of *amicus* briefs.

on preemption under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), 42 U.S.C. §§ 300aa-1 *et seq.*—are engaged in commerce in each of the 50 states. The Chamber's membership includes millions of businesses that are subject in varying degrees to a wide range of federal regulatory schemes that expressly preempt state and local laws. As a result, the Chamber is uniquely suited to offer a broader perspective on preemption and keenly interested in ensuring that the regulatory environment in which its members operate is a consistent one.

INTRODUCTION AND SUMMARY OF ARGUMENT

The court of appeals' bottom-line conclusion—that state-law claims challenging the design of covered vaccines are preempted, whether they sound in negligence or in strict liability—undoubtedly is correct, and respondent's brief addresses in detail why. Rather than reprising at length the features of the Vaccine Act's text, structure, and history, all of which support the court of appeals' reading of Section 22(b)'s preemptive scope, we focus on a problematic and more broadly applicable aspect of the decision below: the court's use of a presumption against preemption in the express preemption context, which unnecessarily cluttered its reasoning. We suggest that there is less to the presumption than meets the eye and that there is little basis for applying a presumption against preemption once Congress has expressly stated its intent to preempt state law.

Particularly in the context of express preemption, the presumption against preemption is fundamentally at odds with central principles of preemption law and statutory interpretation. It is difficult to reconcile with the settled understanding that

preemption turns on congressional intent. A presumption that must yield to any indicia of Congress's preemptive purpose—as ascertained through the usual methods of statutory construction—has very limited application. Thus, one unsurprisingly finds that the Court often ignores the presumption or applies it to no discernable effect, suggesting that the presumption is of limited utility as a practical matter. Other courts struggling to apply this Court's jurisprudence have similarly encountered difficulties trying to make sense of the presumption and deciding how much weight to afford it. Because the presumption is logically ungrounded and has been applied in a haphazard fashion, this case presents an excellent opportunity to reexamine the applicability of the presumption and clarify that express preemption provisions should simply be given a fair reading, with a thumb neither on the side favoring preemption nor that disfavoring it.

Petitioners and some of their *amici* assert that the presumption against preemption is justified in order to protect the traditional prerogatives of the States. Pet. Br. 40-41; Br. of the American Association for Justice, *et al.* (AAJ Br.), at 4-8; Br. of Kenneth W. Starr and Erwin Chemerinsky (Starr & Chemerinsky Br.), at 6-13. The threat to federalism they invoke is exaggerated, while the remedy they propose—the presumption against preemption—endangers other constitutional values. When Congress includes an express preemption clause in a statute (as it did in the Vaccine Act), Congress's intent to displace state law is obvious and the only remaining issue is the *extent* of preemption intended. This is an issue of statutory interpretation, and does not implicate our system of federalism. Whatever the force of the view that matters of federal law should

generally be approached with due regard for the States' traditional spheres of responsibility, once Congress has already explicitly stated its intent to preempt state law, the balance that Congress has articulated should not lightly be second-guessed by courts or disrupted by interpretive "presumptions." It is, after all, in the political branches that the Constitution has vested the prerogative of refining the balance between the respective roles of the States and of the Federal government. That is the unmistakable import of the Supremacy Clause, which declares Federal law the "supreme Law of the Land * * * any Thing in the * * * Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2.

Thus, once Congress has validly enacted a preemption provision pursuant to one of its enumerated powers (and nobody disputes that the Vaccine Act falls squarely within the heartland of the Commerce Clause power), application of a presumption against preemption has no legitimate purpose. When courts adopt crabbed readings of statutory language solely in order to avoid finding preemption, they frustrate Congress's purpose in establishing a uniform federal regulatory regime—a congressional function that takes on additional importance when the alternative to federal regulation is a patchwork of inconsistent state regulation. This very case aptly illustrates how federalism is disserved by the systematic application of a presumption against preemption in express preemption cases. Even one state's choice to impose expansive liability on vaccine manufacturers might well result in the withdrawal of a manufacturer from the national marketplace, thus leading to "the very real possibility of vaccine shortages" nationwide that prompted Congress to enact the Vaccine Act. H.R. REP. No. 99-908, at 7, *reprinted in*

1986 U.S.C.C.A.N. 6344. Allowing individual states to undermine the availability of life-saving products in other states does not advance the cause of federalism a single iota.

Finally, even if a presumption against preemption *ever* had a role to play as a tiebreaker (*e.g.*, when the ordinary tools of statutory construction are in equipoise and the reading disfavoring preemption is truly "*just as plausible*" as the one favoring preemption), that would certainly not be *this* case. See *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (emphasis added); Resp. Br. 44. As the court of appeals correctly concluded, Congress's intent to preempt state-law claims relating to the design of covered vaccines is plain on the face of the Vaccine Act's express preemption provision, and is further confirmed by the structure and legislative history of that statute. There is no countervailing reason to believe that Congress would have wanted to preserve the claims asserted by petitioners. Petitioners and their *amici* thus find themselves in the position of asking this Court to adopt a strained reading of Section 22(b) of the Vaccine Act in order to resurrect their barred design-defect claims.[2] This is an easy

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[2] Curiously, petitioners have nothing to say about a supposed presumption against preemption when it comes to interpreting *Section 22(e)*, which preempts state laws that limit individuals from bringing suit against manufacturers when such claims otherwise would not be preempted by *Section 22(b)*. See 42 U.S.C. § 300aa-22(e). Because a "narrow" reading of the preemptive scope of Section 22(b) necessarily implies a "broad" reading of Section 22(e), petitioners' reliance on the presumption is manifestly unprincipled. Petitioners would have this Court apply it as a one-way ratchet—only when it would expand the claims available to plaintiffs under state law.

case—all the more so, once the presumption against preemption has been laid to rest in the express preemption context.

ARGUMENT

The court of appeals began its analysis by declaring that courts must resolve cases like this one by applying a presumption against preemption. See Pet. App. 15a. It concluded that even when viewed through the lens of the presumption against preemption, the Vaccine Act's express preemption provision must be read to bar any state-law claim that seeks recovery for the side effects of a covered vaccine that was "properly prepared and was accompanied by proper directions." 42 U.S.C. § 300aa-22(b)(1). In categorically deeming as "unavoidable" those injuries and deaths resulting from properly manufactured and adequately labeled vaccines, Congress "made it clear" that design-defect claims (whether sounding in negligence or in strict liability) are preempted. See Pet. App. 33a-34a & n.9. Although the court of appeals' (correct) conclusion on this point follows whether or not the presumption against preemption is applied, the Court should take this opportunity to clarify that the presumption should have played no role in the analysis of Section 22(b) of the Vaccine Act.

I. A Presumption Against Preemption Is Not Appropriately Applied In Express Preemption Cases Such As This One.

The application of the presumption against preemption has not been without controversy. In some cases, the Court has applied the doctrine when interpreting express preemption provisions. See, *e.g.*, *Altria Group*, 129 S. Ct. at 543; *Bates*, 544 U.S. at

449; *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). But as recently as the Court's 2008 decision in *Riegel*, the majority held that the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act preempted the plaintiff's state-law claims without even mentioning the presumption against preemption. See 552 U.S. at 330; see also page 10 & nn. 5-6, *infra*. And a number of current members of the Court have explicitly rejected the presumption's applicability in interpreting the scope of express preemption provisions. See, *e.g.*, *Altria Group*, 129 S. Ct. at 558 (Thomas, J., dissenting) ("[T]here is no authority for invoking the presumption against pre-emption in express pre-emption cases."); *Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part); *Cipollone*, 505 U.S. at 544 (Scalia, J., concurring in the judgment in part and dissenting in part); see also *Engine Mfrs. Ass'n* v. *S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 256 (2004) (noting that "not all Members of this Court agree" on the "application" of the "presumption against pre-emption") (internal quotation marks omitted). There is considerable illogic in application of the presumption here.

A. Applying the presumption in the presence of an express preemption provision conflicts with the central, universally acknowledged rule governing preemption cases: "[p]re-emption fundamentally is a question of congressional intent." *English* v. *Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990).[3] The "task of

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[3] See, *e.g.*, *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 96 (1992) (plurality opinion); *Cipollone*, 505 U.S. at 545 (Scalia, J., concurring in the judgment in part and dissenting in part); *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 208 (1985);

statutory construction must in the first instance focus on the plain wording of the [express preemption] clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 62-63 (2002) (internal quotation marks omitted). Thus, even decisions that have forcefully stated the presumption have gone on to recognize that the Court's "analysis of the scope of [a] statute's pre-emption is guided by [the] oft-repeated comment * * * that '[t]he purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Lohr*, 518 U.S. at 485-486 (quoting *Cipollone*, 505 U.S. at 529 n.27). "As a result, any understanding of the scope of a pre-emptive statute must rest primarily on 'a fair understanding of congressional purpose.'" *Ibid.*; see also *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins.*, 514 U.S. 645, 655 (1995).

When Congress has made its preemptive intent known through "explicit statutory language," the Court's task is "an easy one." *English*, 496 U.S. at 79. The Court's "ultimate task * * * is to determine whether state regulation is consistent with * * * the statute as a whole (*Gade*, 505 U.S. at 98 (plurality opinion)), and Congress's "pre-emptive intent" may be expressed through the "statute's express language or through its structure and purpose" (*Altria Group*, 129 S. Ct. at 543). It is settled that "[i]f the intent of Congress is clear, that is the end of the matter; for the court * * * must give effect to the unambiguously expressed intent of Congress." *FMC Corp.* v. *Holliday*, 498 U.S. 52, 57 (1990) (internal quotation marks omitted). Thus, any presumption against preemption

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Hillsborough County v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 714 (1985).

"dissolves once there is conclusive evidence of intent to pre-empt in the express words of the statute itself." *Cipollone*, 505 U.S. at 545 (Scalia, J., concurring in the judgment in part and dissenting in part). "Under the Supremacy Clause, * * * [the Court's] job is to interpret Congress's decrees of pre-emption neither narrowly nor broadly, but in accordance with their apparent meaning." *Id.* at 544. The judicial task is to "determine which state-law claims [the statute] pre-empts, *without slanting the inquiry* in favor of either the Federal Government or the states." *Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part) (emphasis added).

Because it is fundamental that preemption turns on congressional intent—and because the Court conducts an inquiry into preemption by "begin[ning] with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose" (*FMC Corp.*, 498 U.S. at 57 (internal quotation marks omitted))—any presumption regarding preemption must yield to the ordinary tools of statutory construction when Congress has enacted an express preemption provision. This analysis starts with the text of the statute, read (only if necessary) in light of the statute's structure, purpose, regulatory context, and legislative history, and leaves no place for the "unreasonabl[e] interpret[ation of] expressly pre-emptive federal laws in the name of" a supposed presumption against preemption. *Altria Group*, 129 S. Ct. at 558 (Thomas, J., dissenting).

B. In light of the primacy of congressional intent, it is hard to discern what work the presumption actually does in practice. To be sure, there are a fair

number of cases in which the Court has recited the familiar phrases acknowledging the presumption.[4] But there are numerous express preemption decisions—most recently *Riegel*, 552 U.S. 312—in which the Court has "said not a word about 'a presumption against * * * preemption, * * * that was to be applied to construction of the text [of such a provision]." *Cipollone*, 505 U.S. at 546 (Scalia, J., concurring in the judgment in part and dissenting in part).[5] In fact, the Court regularly has "refrained from invoking the presumption in the context of express pre-emption." *Altria Group*, 129 S. Ct. at 556 (Thomas, J., dissenting).[6] This is true both in cases holding state laws not to be preempted,[7] and in those finding them to be preempted.[8] And even when the presumption against

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[4] *E.g.*, *Altria Group*, 129 S. Ct. at 543; *Lohr*, 518 U.S. at 485; *New York State Conference of Blue Cross & Blue Shield Plans*, 514 U.S. at 655; *Cipollone*, 505 U.S. at 518; *English*, 496 U.S. at 79; *Hillsborough County*, 471 U.S. at 715.

[5] Justice Scalia cited *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) and *Norfolk & W. Ry. Co.* v. *American Train Dispatchers Ass'n*, 499 U.S. 117 (1991).

[6] Justice Thomas cited *Rowe* v. *New Hampshire Motor Transp. Ass'n*, 552 U.S. 364 (2008); *Engine Mfrs. Ass'n*, 541 U.S. 246; *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Locke*, 529 U.S. 89; and *Geier*, 529 U.S. 861. There are many others. *E.g.*, *Freightliner Corp.* v. *Myrick*, 514 U.S. 280 (1995); *Am. Airlines, Inc.* v. *Wolens*, 513 U.S. 219 (1995); *FMC Corp.* v. *Holliday*, 498 U.S. 52 (1990); *La. Pub. Serv. Comm'n* v. *FCC*, 476 U.S. 355 (1986); *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691 (1984); *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141 (1982); *Malone* v. *White Motor Corp.*, 435 U.S. 497 (1978).

[7] See, *e.g.*, *Freightliner Corp.*, *supra*; *La. Public Service Comm'n*, *supra*; *Malone*, *supra*.

[8] See, *e.g.*, *Rowe*, *supra*; *Engine Mfrs. Ass'n.*, *supra*; *Buckman*, *supra*; *Locke*, *supra*; *Geier*, *supra*; *Am. Airlines*, *supra*; *FMC*

preemption is acknowledged, it has been applied by the Court in manner that is far from uniform. Although it has been said to be inapplicable "when the State regulates in an area where there has been a history of significant federal presence" (*Locke*, 529 U.S. at 108), the presumption at other times is said to govern all federal legislation (*Maryland* v. *Louisiana*, 451 U.S. 725, 746 (1981)) or legislation that touches fields where there has been a "historic presence of state law" (*Levine*, 129 S. Ct. at 1194-95 & n.3).

Because the Court's decisions have done little to clarify the question of what it means to interpret an express preemption provision narrowly, and when this must be done, it is unsurprising that confusion and inconsistency dominate other courts' attempts to apply the presumption against preemption. See *Farina* v. *Nokia*, 578 F. Supp. 2d 740, 754-55 (E.D. Pa. 2008) (noting that "Supreme Court precedents have not been consistent" and that "[h]ow this presumption against preemption is to be applied" has varied widely depending on context). The Court's recent 5-4 decision in *Altria Group* is unlikely to dispel this confusion. Although the majority opinion stated in passing that the presumption against preemption applies to express as well as implied preemption analyses, the Court did not explain how that result could be reconciled with *Riegel* or the widely accepted tenet that congressional intent is the ultimate touchstone

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Corp., *supra*; *Capital Cities Cable*, *supra*; *Fid. Fed. Sav.*, *supra*. One study found that the percentage of this Court's cases in which preemption of state common-law tort claims was found actually *increased* following *Cipollone*. Michael S. Greve & Jonathan Klick, *Preemption in the Rehnquist Court: A Preliminary Empirical Assessment*, 14 SUP. CT. ECON. REV. 43, 57 (2006).

of the preemption inquiry. Notwithstanding *Altria*, a few courts since that decision have ignored the presumption in their analyses of express preemption provisions.[9] And even when lower courts do dutifully recite the presumption as an abstract proposition of law, they often decide the case using traditional tools of statutory interpretation without further reference to the presumption in the court's analysis of the statute, or find that the presumption is inapplicable because of the subject matter of the state regulation.[10] All this breeds needless complexity.

In the end, we are not aware of any decision in which the Court found evidence of congressional intent that would have been held sufficient in other contexts, but was rejected because it did not overcome the presumption against preemption. For all of the controversy, the presumption seems to make lit-

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[9] See, *e.g.*, *Chae* v. *SLM Corp.*, 593 F.3d 936, 944 (9th Cir. 2010) (referencing "assumption" of non-preemption only during discussion of conflict preemption); cf. *Zimmerman* v. *Bd. of County Comm'rs*, 218 P.3d 400, 430 (Kan. 2009) ("In *the absence of express preemption* in a federal law, there is a strong presumption that Congress did not intend to displace state law") (emphasis added and internal quotation marks omitted).

[10] *E.g.*, *Colo. Interstate Gas Co.* v. *Wright*, No. 09-4031, 2010 WL 1488934, at *16 (D. Kan. Apr. 13, 2010) (party was not entitled to "claim the benefit of a presumption against preemption" because natural gas transportation was an area "where there has been a history of significant federal presence") (internal quotation marks omitted); *Brown* v. *United Air Lines, Inc.*, 656 F. Supp. 2d 244, 251-52 (D. Mass. 2009) (declining to "imply broad exceptions to the preemption provision" even "for areas of traditional state concern," such as employment law); *Ophir* v. *City of Boston*, 647 F. Supp. 2d 86, 91-92 (D. Mass. 2009) (presumption "not triggered" when state "regulate[d] in an area of significant federal presence [such as] fuel economy").

tle difference to how *this* Court decides express preemption cases. But *other* courts have to struggle with faithfully applying this Court's precedent.[11] It is time to inter the presumption against preemption in this context and to bring to an end the mischief it has occasioned. Express preemption provisions should be analyzed according to the normal tools of statutory interpretation.

II. The Federalism Concerns Asserted By Some Of Petitioners' *Amici* Cannot Justify A Presumption Against Preemption.

The presumption against preemption often is said to rest on "principles of federalism and respect for state sovereignty." *Cipollone*, 505 U.S. at 533 (Blackmun, J., concurring in part and dissenting in part). True to form, some *amici* pick up on this theme, asserting that the presumption is necessary to "protect state sovereignty and to ensure the proper functioning of the political safeguards of federalism." Starr & Chemerinsky Br. 2. This traditionally ad-

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[11] A case in point is *Ferrari* v. *American Home Products Corp.*, 650 S.E.2d 585 (Ga. App. 2007), which took "one part of the [presumption against preemption as articulated in *Bates*] out of its context, and [gave] it broader scope than is appropriate," "so as to make the presumption against preemption irrebuttable." *Am. Home Products Corp.* v. *Ferrari*, 668 S.E.2d 236, 238-39 (Ga. 2008) (internal quotation marks omitted). In fact, the confused application of a presumption against preemption in both the Georgia appellate court and the Georgia Supreme Court in *Ferrari* contributed to those courts' erroneous conclusion that the Vaccine Act preempted design-defect claims only on a case-by-case basis. See Br. for U.S., *Am. Home Products Corp.* v. *Ferrari*, No. 08-1120 (Jan. 29, 2010), at 8, *available at* 2010 WL 342143; Br. for The Chamber of Commerce of the United States of America, *Am. Home Products Corp.* v. *Ferrari*, No. S0761708 (Ga. Mar. 3, 2008), *available at* 2008 WL 4992164.

vanced rationale for the presumption does not, however, stand up to scrutiny. And it certainly does not constitute a legitimate reason for imposing a "clear statement" limitation on the scope of express preemption provisions.

A. Contrary to *amici*'s protestations (*e.g.*, Starr & Chemerinsky Br. 6-11; AAJ Br. 7), no federalism concerns inhere in the operation of express preemption provisions, because preemption of state law is a necessary consequence of the constitutional plan—in particular, the interplay between Congress's legislative powers and the Supremacy Clause. See *New York* v. *United States*, 505 U.S. 144, 156 (1992) ("If a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States."). Regardless of how "compelling" an interest a State has in preservation of its law, "under the Supremacy Clause, from which our pre-emption doctrine is derived, any state law"—even one "clearly within a State's acknowledged power, which interferes with or is contrary to federal law"—"must yield." *Gade*, 505 U.S. at 108 (internal quotation marks omitted).

Valid federal legislation trumps state law. U.S. CONST. art. VI, cl. 2. The Supremacy Clause's purpose was "to remedy one of the chief defects in the Articles of Confederation by instructing courts to resolve state-federal conflicts in favor of federal law." David Sloss, *Constitutional Remedies for Statutory Violations*, 89 IOWA L. REV. 355, 402 (2004). There is no historical "support * * * for the conclusion that the [F]ramers intended any * * * presumption to be read into [the Supremacy Clause]." Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C.

DAVIS L. REV. 1, 30 (2001).[12] To the contrary, there is considerable evidence that the Framers would have regarded the Supremacy Clause as *rejecting* "a general presumption that federal law does not contradict state law." Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 293 (2000). In other words, the Supremacy Clause was "designed precisely to eliminate any residual presumption" against implied repeals of state law in the face of contradictory federal law. Jack Goldsmith, *Statutory Foreign Affairs Preemption*, 2000 SUP. CT. REV. 175, 184.

When all is said and done, the issue of constitutional magnitude implicated by the presumption against preemption is not the *vertical* structure of federal-state relations upon which petitioners and their *amici* dwell. After all, "'[t]he relative importance to the State of its own law is not material when there is a conflict with valid federal law, for the

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[12] The Court's earliest Supremacy Clause cases give no indication that any sort of presumption against preemption should govern analysis of the validity of state laws. See, *e.g.*, *Martin* v. *Hunter's Lessee*, 14 U.S. (1 Wheat.) 304, 343-344 (1816) ("the legislatures of the states are, in some respects, under the control of congress, and in every case are, under the constitution, bound by the paramount authority of the United States"); *Ware* v. *Hylton*, 3 U.S. (3 Dall.) 199 (1796) (applying no presumption in case where state criminal law was superseded by treaty). Nor did the Court in these early cases suggest that special treatment was appropriate for state laws involving exercise of the State's traditional police powers. To the contrary, Chief Justice Marshall took pains to explain for the Court that, if a state's laws "come into collision" with federal law by "being contrary to" acts of Congress, it would be immaterial that the laws were passed "in virtue of a power to regulate [the state's] domestic trade and police." *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 210 (1824).

Framers of our Constitution provided that the federal law must prevail.'" *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Free* v. *Bland*, 369 U.S. 663, 666 (1962)). And "to the extent that other federalism questions remain—the wisdom of national regulation, the balance between regulatory uniformity and policy innovations, etc.—those questions are, by constitutional design, to be *answered by Congress*." Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2092 (2000) (emphasis added).[13]

Rather, the presumption against preemption aggrandizes the judicial branch over the political branches—a classic *horizontal* clash of authority. Courts depart from the proper judicial role when they apply an interpretive presumption at the expense of concrete indicia of congressional intent. The "systematic[] favor[ing]" of "one result over another" in analyzing preemption questions "risk[s] an illegitimate expansion of the judicial function" by "disrupt[ing] the constitutional division of power between federal and state governments" and by "rewrit[ing] the laws enacted by Congress." Dinh, *supra*, 88 GEO. L.J. at 2092. Respect for the political branches counsels in favor of not placing a judicial thumb on the scales when interpreting the reach of an express preemption provision.

B. Because the Supremacy Clause of the Constitution points in *favor* of, not *against*, preemption,

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[13] Moreover, as a practical matter, "States are among the most influential of interest groups in the federal legislative process," and are therefore eminently well-positioned to raise with Congress their concerns about the preemptive scope of a given statute. Goldsmith, *supra*, 2000 SUP. CT. REV. at 178, 186.

a clear statement rule is not appropriate in the express preemption context. *Amici* therefore are mistaken when they suggest that courts should insist that Congress express a "clear and manifest preemptive purpose" (Starr & Chemerinsky Br. 7) before giving full effect to an express preemption provision. Such a rule would mesh at best uneasily with the clear statement rules that the Court has applied in other contexts.

As Justice Scalia has explained, clear statement rules are designed principally "to ensure that, absent unambiguous evidence of Congress's intent, extraordinary constitutional powers are not invoked, or important constitutional protections eliminated, or seemingly inequitable doctrines applied. *Cipollone*, 505 U.S. at 546-547 (Scalia, J., concurring in the judgment in part and dissenting in part). Such clear statement rules ordinarily are applied to guarantee that Congress actually has focused on achieving a particular result that gives rise to constitutional concern.[14] But there is nothing extraordinary or concerning about express preemption, which is a routine consequence of the constitutional design that does not implicate any genuine federalism concerns.[15]

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[14] *E.g.*, *Kimel* v. *Fla. Bd. of Regents*, 528 U.S. 62, 73 (2000) (Congress's intent to abrogate Eleventh Amendment sovereign immunity must be "unmistakably clear in the language of the statute") (internal quotation marks omitted).

[15] A presumption against preemption in the express preemption context would be conceptually incoherent in yet another respect: namely, it would have to coexist alongside the notion of *implied* preemption, under which federal laws have preemptive effect even "[w]here Congress likely did not focus specifically on the matter," so long as a ruling against preemption would produce an "anomalous result." *Lohr*, 518 U.S. at 504 (Breyer, J.,

The presumption against preemption forces Congress to be *doubly* explicit about drafting legislation that potentially encroaches on traditional areas of state authority. According to the presumption's proponents, it is not enough that Congress be explicit about its *intent* to preempt—by assumption, the fact that Congress has enacted an express preemption provision does not suffice. Under the unworkable approach petitioners' *amici* propose, Congress would be required to go still further, and anticipate every area of potential overlap between the federal and state regulatory regimes. As Justice Scalia explained in a related context, "the result is extraordinary: The statute that says *anything* about pre-emption must say *everything*; and it must do so with great exactitude, as any ambiguity concerning its scope will be read in favor of preserving state power." *Cipollone*, 505 U.S. at 548 (Scalia, J., concurring in the judgment in part and dissenting in part).

Thus, a Congress intent on displacing state law would be left with one of two unpalatable options: (1) it must enumerate and specifically target every conceivable state-law regime subject to preemption,[16] or (2) it must enact a deliberately over-inclusive preemption provision that sweeps so broadly as to deprive courts of the interpretative latitude to find

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concurring). When implied preemption is at issue, Congress *by definition* has not clearly spoken to its intent to preempt, yet the Court remains willing to find preemption. This makes it especially odd to impose a clear statement rule when dealing with an express preemption provision.

[16] This would at most be a partial solution. Practically speaking, States would be emboldened to strategically re-characterize their law in order to wedge open a supposed gap in preemptive coverage, notwithstanding Congress's plainly expressed intent to preempt. See Nelson, *supra*, 86 VA. L. REV. at 290-91.

any possible "ambiguity" or alternative "reading that disfavors pre-emption." Cf. *Bates*, 544 U.S. at 449. Neither outcome serves federalism.

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Application of the presumption against preemption in the express preemption context needlessly invites courts to engage in a battle that they should not fight and cannot win. The Constitution entrusts to the political branches the task of allocating regulatory authority between the States and the federal government. Constitutional principle and pragmatism align in this instance and call for the same result: forswearing further reliance on a presumption against preemption that can serve only to distort congressional intent.

III. Section 22(b) Of The Vaccine Act Preempts Petitioners' Design-Defect Claims.

To be clear, the decision below *did* apply the presumption against preemption and concluded that "even in light of the presumption against preemption," there was "clear and manifest" evidence that Congress intended to preempt petitioners' design-defect claims. See Pet. App. 30a. We submit, though, that the same result could have been reached more straightforwardly without the analytical underbrush of the presumption. The appropriate function of the courts in this, as in any other, issue of statutory interpretation, is to identify the *best* (*i.e.*, most plausible) reading of the *actual* statute (see Br. for U.S., *Am. Home Products Corp.* v. *Ferrari*, No. 08-1120 (Jan. 29, 2010), at 9, *available at* 2010 WL 342143)—not to approach the statute with a blue pencil and chide Congress for failing to "speak with the discrimination of an Oxford don." Cf. *Davis* v. *United States*,

512 U.S. 452, 459 (1994) (internal quotation marks omitted).

When employed in the service of gaining a "fair understanding of congressional purpose" (*Lohr*, 518 U.S. at 486-87), the ordinary indicia of legislative intent point in a single direction: that Congress eschewed the case-by-case approach sought by petitioners in favor of a categorical rule deeming "unavoidable" any residual injuries once it has been established that a covered vaccine was properly manufactured and adequately labeled. All state-law claims challenging such injuries are, accordingly, preempted by the Vaccine Act.

A. Section 22(b) of the Vaccine Act provides that "[n]o vaccine manufacturer shall be liable * * * for damages arising from a vaccine-related injury or death * * * if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." In substance, petitioners assert that courts should decide, on a case-by-case basis, whether the side effects in question actually were unavoidable. They contend that the Vaccine Act preempts only claims with respect to injuries or deaths that could not have been prevented by a safer alternative design. Pet. Br. 31.[17]

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[17] Petitioners thus implicitly recognize that Section 22(b) must preempt at least *some* design-defect claims. Section 22(b) would be a dead letter otherwise, since by its terms it permits manufacturing-defect and failure-to-warn claims to proceed. There would be no point to a provision that *also* excluded from its preemptive reach the only remaining category of products liability claims, those alleging a design defect. See generally Restatement (Third) of Torts: Products Liability § 2 ("A product is defective when, at the time of sale or distribution, it contains a

Such a construction cannot be squared with the statutory language. It reads out of the statute the phrase introduced by "even though," and therefore "render[s] superfluous" (*Astoria Fed. Sav. & Loan Ass'n* v. *Solimino*, 501 U.S. 104, 112 (1991)) the very language Congress included in the statute to delimit by contrast *avoidable* causes of vaccine-related injury—namely, those caused by manufacturing defects or improper directions and warnings. Injuries that did *not* result from these avoidable causes were considered by Congress to be "unavoidable" within the meaning of the Vaccine Act and thus compensable, if at all, under the administrative scheme established.

B. The legislative history of Section 22(b) confirms that Congress intended the Vaccine Act to preempt all design-defect claims, regardless of whether the plaintiff could point to a feasible alternative design. The Committee Report on the Vaccine Act makes clear that Section 22(b) was meant to preserve a judicial remedy only for state-law claims alleging defects in the vaccine's manufacture or accompanying labeling, while preempting all design-defect claims.[18]

The Report explains that "if [claimants] cannot demonstrate under applicable law either that a vac-

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manufacturing defect, is defective in *design*, or is defective because of *inadequate instructions or warnings*.") (emphasis added).

[18] As respondent explains, petitioners erroneously place stock on "legislative history" issued *after* the original enactment of the Vaccine Act in connection with its funding. See Resp. Br. 48-51; see also *United States* v. *Price*, 361 U.S. 304, 313 (1960) ("[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one.").

cine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, *not the tort system*." H.R. REP. No. 99-908, at 26 (emphasis added). Congress thus intended to relegate design-defect claims to the administrative compensation system created by the Vaccine Act, as long as the covered vaccine causing injury was properly manufactured and adequately labeled. In making this determination, Congress was guided by the policy of Comment k of Section 402A of the Restatement (Second) of Torts, which the Committee believed was "appropriate and necessary as the policy for civil actions seeking damages in tort" for vaccine-related injures.[19] *Id.* at 26.

Faced with this inconvenient legislative history, petitioners and their *amici* try to explain it away with a superficially appealing syllogism, which at its core is as follows:

- *Major premise*: Congress sought merely to "codify" or "incorporate" Comment k in enact-

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[19] That comment, titled "[u]navoidably unsafe products," states in relevant part:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. * * * Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. * * * The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

ing Section 22(b). Pet. Br. 39; Br. of Mark A. Geistfeld (Geistfeld Br.) at 6.

- *Minor premise*: At the time Section 22(b) was adopted, the prevailing view of courts applying the Restatement's approach to products liability was to conduct a case-by-case analysis of whether the prescription product before the court was "unavoidably unsafe" within the meaning of Comment k. Pet. Br. 30-31 & n.16; Geistfeld Br. 10-12, 19.[20]
- *Conclusion*: Since Congress is presumed to have been aware of the judicial gloss on Comment k, Section 22(b) calls for the determination, on a case-by-case basis, of

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[20] Although not our focus, we note that petitioners' reconstruction of the state of products liability law in 1986 is highly selective. "[W]hile some courts concluded that a case-by-case analysis was necessary to determine whether a prescription drug was unavoidably unsafe, *i.e.*, that it could have been made safer by a better design, others concluded that prescription drug manufacturers were generally not liable for design defect claims." *Militrano ex rel. Militrano* v. *Lederle Labs.*, 769 N.Y.S.2d 839, 844-45 (N.Y. Sup. Ct. 2003) (internal citations omitted); see also Resp. Br. 43-44 & n.25. A not-inconsiderable number of courts had concluded that prescription drugs (such as vaccines) were, as a class, unavoidably unsafe products, and therefore effectively immunized from design-defect liability under Comment k. See David E. Chamberlain, Comment, *The Diminishing Role of Negligence in Manufacturers' Liability for Unavoidably Unsafe Drugs and Cosmetics*, 9 ST. MARY'S L.J. 102, 115 (1977). As even one of petitioners' own *amici* reluctantly recognizes, the "great majority of courts" do in fact invoke "comment k to exempt from strict liability the manufacturers of pharmaceutical projects," presumably on the notion that comment k "define[s]" pharmaceutical products as "unavoidably unsafe." Geistfeld Br. 12 (internal quotation marks omitted).

> whether or not the vaccine in question qualifies as an "[u]navoidably unsafe product."

The major premise of this argument is demonstrably false. Petitioners' assumption to the contrary, Section 22(b) does not merely direct courts to apply Comment k as the *substantive rule of decision* in design-defect claims brought against vaccine manufacturers. Rather, in enacting Section 22(b), Congress intended to articulate the across-the-board legislative judgment that covered vaccines are "unavoidably unsafe" within the meaning of Comment k. See Resp. Br. 40-42. As the Committee Report explains:

> The Committee has set forth Comment K * * * because it intends that the *principle* in Comment K regarding "unavoidably unsafe" products * * * apply to the vaccines covered in the bill and that *such products not be the subject of liability in the tort system.*

H.R. Rep. No. 99-908, at 26 (emphases added).

In other words, what Congress intended in enacting Section 22(b) was to deem *all* covered vaccines to be "unavoidably unsafe" products to which the "principle" of Comment k applied.[21] That "principle"—no liability for properly manufactured and adequately labeled products that are unavoidably unsafe—operates to preclude the availability of design-defect liability for covered vaccines *as a class*. What "un-

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[21] Congress thus viewed covered vaccines as paradigmatic examples of "unavoidably unsafe" products—*i.e.*, those "which in the present state of human skill and knowledge" cannot be made truly "safe," but which nonetheless are of such great social utility that their continued marketing and use are justified. H.R. REP. No. 99-908, at 26.

avoidably unsafe" or Comment k meant to *state courts* in 1986 is a red herring, since "Congress made it clear what *it* intended when it invoked comment k." Pet. App. 34a n.9 (emphasis added); see Resp. Br. 41-42.

* * *

In enacting Section 22(b) of the Vaccine Act, Congress made the judgment that it was necessary to protect vaccine manufacturers from the unpredictability and expense of design-defect claims in the tort system, so as to preserve the continued availability of life-saving vaccines. Congress did not leave it up to the courts to decide on a state-by-state, case-by-case basis whether a given vaccine's design was design because of the existence of a feasible alternative design. All of the usual tools of statutory interpretation—*e.g.*, the plain import of the text, structure, and legislative history of the Vaccine Act—point towards this understanding of Section 22(b). The conclusion that petitioners' design-defect claims are preempted should, accordingly, follow without any additional analytical detours, such as a supposed presumption against preemption.

CONCLUSION

The judgment should be affirmed.

Respectfully submitted.

ROBIN S. CONRAD
AMAR D. SARWAL
National Chamber Litigation Center, Inc.
1615 H Street, N.W.
Washington, DC 20062
(202) 463-5337

DAVID M. GOSSETT
Counsel of Record
BRIAN J. WONG
Mayer Brown LLP
1999 K Street, NW
Washington, DC 20006
(202) 263-3000
dgossett@mayerbrown.com

Counsel for Amicus Curiae

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AMICUS CURIAE BRIEF

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IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ,
PARENTS AND NATURAL GUARDIANS OF
HANNAH BRUESEWITZ, A MINOR CHILD,
AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES,
WYETH-AYERST LABORATORIES, WYETH LEDERLE,
WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Third Circuit

BRIEF OF MARK A. GEISTFELD AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

MARK A. GEISTFELD
Counsel of Record
New York University School of Law
40 Washington Square S.
New York, New York 10012
(212) 998-6683

June 1, 2010

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INTEREST OF *AMICUS CURIAE*[1]

Mark A. Geistfeld is the Sheila Lubetsky Birnbaum Professor of Civil Litigation at New York University School of Law, where he has been a member of the fulltime faculty since 1991. His primary teaching areas are Insurance, Products Liability, and Torts. He has also taught Law and Economics.

Professor Geistfeld's research addresses the common-law rules governing the prevention of and compensation for physical harms. He has published dozens of articles on a broad range of products liability and tort doctrines. He is the author of two leading legal textbooks, TORT LAW: THE ESSENTIALS (Aspen Pub. 2008); PRINCIPLES OF PRODUCTS LIABILITY (Foundation Press 2006). Professor Geistfeld is also the author of a new casebook, PRODUCTS LIABILITY LAW (Aspen Pub. forthcoming 2011).

The instant case is of central interest to Professor Geistfeld insofar as it involves the interpretation of Restatement (Second) of Torts § 402A comment k (1965).

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* represents that he authored this brief and that no person or entity other than *amicus* made a monetary contribution to the preparation or submission of the brief. *Amicus* represents that counsel for all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amicus* briefs have been filed with the Clerk.

STATEMENT

In the case at issue, petitioners brought suit against respondent Wyeth, Inc., a manufacturer of a whole-cell diptheria-pertussis-tetanus (DPT) vaccine that allegedly caused petitioners' daughter to suffer seizures after receiving a dose of the vaccine. Respondent moved for summary judgment. The United States District Court for the Eastern District of Pennsylvania, Baylson, J., granted the motion. On appeal, the United States Court of Appeals, Third Circuit, Smith, J., affirmed, holding that the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act) expressly preempts both strict liability and negligent design defect claims. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233 (3d Cir. 2009)

In its preemption analysis, the Court of Appeals concluded "that the Vaccine Act reflected the *principle* of Restatement (Second) of Torts § 402A comment k, which states that sellers of certain products, including vaccines, should not be strictly liable for harm caused by their products when it is not possible to make these products entirely safe." *Id.* at 247-248 (footnotes omitted). The Court of Appeals then rejected the interpretation of comment *k* adopted by the Georgia Supreme Court in *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008), *petition for cert. pending*, No. 08-1120 (U.S. filed Mar. 5, 2009), because that interpretation "does not bar any design defect claims." 561 F.3d at 246. Reasoning that the Vaccine Act most plausibly bars at least *some* design defect claims, the Court of Appeals concluded that the Act must expressly preempt *all* such claims. *Id.* at 248.

SUMMARY OF ARGUMENT

The Court of Appeals' preemption analysis rests on a mistaken evaluation of comment *k*. When interpreted by reference to the type of defect of concern to comment *k*, the Vaccine Act bars strict products liability claims only for certain types of manufacturing and design defects defined exclusively in terms of product malfunctions. Moreover, comment *k* does not insulate the seller of an unreasonably dangerous product from liability. Applied to the facts of this case, comment *k*—and the Vaccine Act—does not prevent petitioners from establishing liability for defective design by proving that a reasonable (and safer) alternative design to Wyeth's whole-cell DPT vaccine was available when Hannah Bruesewitz was inoculated.

The Restatement (Second) of Torts § 402A rule of strict products liability is based on case law involving defects that render a product unable to perform its manifestly intended function. The rule originated with contaminated food cases and was gradually extended to other products containing defects that caused the product to malfunction in a self-defeating manner, such as an exploding bottle of soda. Restatement (Second) of Torts § 402A cmt. b.

As § 402A recognizes, liability for this type of unavoidable defect could create problems for products having a primary purpose of health or safety, such as drugs or vaccines posing inherent risks of side effects. The manifest purpose of these products is to promote the consumer's health, and so in the event that an unavoidable side effect causes injury to the consumer, the drug or vaccine has performed in a self-defeating manner that typically would trigger the rule of strict liability for product malfunctions.

Comment *k* recognizes that subjecting these products to strict liability could be socially problematic because the imposition of strict liability would not promote product safety for an "unavoidably unsafe" product. Consequently, it exempts "unavoidably unsafe" products from the § 402A rule of strict products liability. *Id.* cmt. k.

The comment *k* exemption only applies to the § 402A rule of strict products liability and does not otherwise exempt product sellers from negligence liability. The principle of comment *k* bars the application of strict liability only when doing so would undermine the public interest in product safety, whereas negligence liability promotes safety by incentivizing producers to eliminate unreasonably dangerous products from the marketplace. To be sure, negligence liability can threaten the financial viability of producers—a distinct possibility implicit in comment *k*'s retention of liability for inadequate warnings—but this is a consequence inherent in tort law's goal of promoting product safety.

In light of the historical foundation of comment *k*, the corresponding exemption of liability in the Vaccine Act clearly does not bar petitioners' claim for defective design. Petitioners allege that the DPT vaccine is not "unavoidably unsafe" because a reasonable alternative design would reduce the risk of side effects. This tort claim furthers the safety objective of products liability and therefore is not barred by comment *k*.

ARGUMENT

I. The Vaccine Act Incorporates Comment *k* into Its Substantive Provisions

Section 300aa-22 of the Vaccine Act, entitled "Standards of Responsibility," provides:

> (a) General rule
>
> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22.

The language of subsection 22(b)(1) mirrors comment *k* of the Restatement (Second) of Torts § 402A, which exempts "unavoidably unsafe products" from the § 402A rule of strict products liability:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads

> to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper direction and warning, is not defective, nor is it *unreasonably* dangerous. The same is true in particular of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k.

A comparison shows that subsection 22(b)(1) of the Vaccine Act incorporates comment *k*. That subsection provides an exemption from liability for "side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings," a provision substantively

identical to comment *k*'s exemption for vaccines involving an "unavoidable high degree of risk" if the vaccine is "properly prepared, and accompanied by proper directions and warning." *Compare* 42 U.S.C. § 300aa-22 *with* Restatement (Second) of Torts § 402A cmt. k.

This conclusion is fully supported by the legislative history of the Vaccine Act. The House Committee on Energy and Commerce "had jurisdiction over the Vaccine Act and guided the legislation through passage." *Bruesewitz*, 561 F.3d at 247 (citing H.R. Rep. No. 99-908, pt. 1 (1986)). The Committee Report expressly acknowledges that comment *k* is the substantive basis for subsection 22(b)(1) of the Vaccine Act:

> Subsection (b)—Unavoidable Adverse Side Effects; Direct Warnings.—This provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even through the vaccine was properly prepared and accompanied by proper directions and warnings.
>
> *The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding "unavoidably unsafe" products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.* The vaccines addressed in this legislation certainly present the hardest case for the application of Comment K. In such a case, the plaintiff is almost invariably a young child, often badly

> injured or killed, and free from wrongdoing. And, even if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the "innocent" manufacturer if the equally "innocent" child has to bear the risk of loss with no other possibility of recompense.

H.R. Rep. No. 99-908, pt. 1, at 25-26 (emphasis added). In sum, then, the express language of the Vaccine Act and its legislative history both support the conclusion that subsection 22(b)(1) of the Vaccine Act incorporates comment *k*.

II. The Principle of Comment *k*

When the American Law Institute promulgated Restatement (Second) of Torts § 402A in the mid-1960s, it announced a liability rule that was based on cases involving defects defined by a self-defeating product malfunction, such as the exploding bottle of soda at issue in the case that ushered in the era of strict products liability, *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 461 (Cal. 1944) (Traynor, J., concurring). As Professor Michael Green has explained:

> The strict liability proposed by section 402A was not limited to manufacturing defects. Indeed, that section, influenced by its warranty heritage—the then-existing source of strict liability in the law—employed a conceptual framework independent of specific types of defect. Rather than the familiar three-defect world in which we find ourselves today, section 402A contemplated a performance-based idea for defect. If a product performed in a way that revealed a defect—regardless of its source—

> then it was defective. Thus, if a gun went off when being held by its owner without the owner engaging its trigger, the gun was defective and we need not trace the source of that defect.

Michael D. Green, *The Unappreciated Congruity of the Second and Third Tort Restatements on Design Defects*, 74 Brooklyn L. Rev. 807, 812 (2009) (footnote omitted); *see also* Restatement (Second) of Torts § 402A cmt. b (discussing how rule of strict products liability evolved from cases involving the sale of contaminated or "corrupt" food and drink).

Performance-based defects ordinarily stem from construction or manufacturing flaws, but a product malfunction can also be attributable to defective design. *See McCabe v. L.K. Liggett Drug Co.*, 112 N.E.2d 254 (Mass. 1953) (finding that the defendant breached the implied warranty by selling a coffeepot with a design that caused it to explode during normal use); Restatement (Third) of Torts: Products Liability § 3 cmt. b (1998) ("[O]ccasionally a product design causes the product to malfunction in a manner identical to that which would ordinarily be caused by a manufacturing defect.").

Because § 402A was formulated by reference to performance-based defects or product malfunctions, comment *k* addresses the problems that this rule of strict liability could pose for products that have an intended purpose of promoting health or safety. If a drug or vaccine has an unavoidable side effect that injures the user, for example, then in this instance it has functioned in a self-defeating manner that typically would trigger the rule of strict products liability. *Cf. id.* § 3 cmt. b (explaining rule that enables plaintiff to recover without proof of a specific defect

for "situations in which a product fails to perform its manifestly intended function"). The vaccine or drug was supposed to promote the health of the user, but instead it caused injury. Whether such a "malfunction" ought to be governed by the rule of strict liability is the issue addressed by comment *k*. *Cf.* James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision to Section 402A of the Restatement (Second) of Torts*, 77 Cornell L. Rev. 1512, 1541 (1992) (providing "strong evidence" that Dean Prosser, "who was the Reporter for the Second Restatement and who dominated the development of section 402A," developed comment *k* out of concern "that manufacturers of even well-designed drugs of unquestioned social utility would be subject to liability for idiosyncratic drug reactions whose dangers were known and warned against").

When comment *k* is interpreted by reference to defects defined by a product malfunction, its principle becomes readily apparent. As *amicus* has explained at length elsewhere:

> To understand comment *k*, we can consider [its invocation of] the "outstanding example" of an "unavoidably unsafe" product—the Pasteur rabies vaccine. Even when the manufacturer has "properly prepared" the vaccine, it can be contaminated with brain tissue, creating dangerous side effects for the user. [Rogers v. Miles Lab., 802 P.2d 1346, 1350-51 (Wash. 1991).] Consequently, the rabies vaccine can have "no assurance ... of purity of ingredients," because these "products ... in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Impurities, like those in contami-

nated food, are a common form of construction or manufacturing defect subject to strict liability, but the seller of "properly prepared" rabies vaccine accompanied by a "proper warning" is not subject to liability for injuries caused by contaminated vaccine. The vaccine treats a disease that "invariably leads to a dreadful death," so the seller should not incur liability for supplying "the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk" [as per comment *k*].

... The express rationale for doing so, however, would seem to apply to numerous other products. The "present state of human knowledge" does not make it possible to have perfect quality-control measures in the construction of automobiles. These products are "useful and desirable" while being "attended with a known and apparently reasonable risk." Automobiles would appear to satisfy all of the express requirements for an "unavoidably unsafe" product under comment *k*, but the limitation of strict liability no longer seems so sensible.

The courts have not exempted automobile sellers from strict liability. "While comment *k* could be read to apply to other products, it does not really give us any examples or suggest other areas where the policy balancing is precisely the same. For this reason, the courts and most commentators have assumed that comment *k* relates to pharmaceuticals ...." [Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy*

> *Behind Comment k*, 42 Wash. & Lee L. Rev. 1139, 1141 (1985).] The practical effect of this interpretation has been enormous. A "great majority" of courts have relied upon comment *k* to exempt from strict liability the manufacturers of pharmaceutical products. [David G. Owen et al., 2 MADDEN & OWEN ON PRODUCTS LIABILITY § 22:3, at 558 (3d ed. 2000).]
>
> This interpretation of comment *k* is problematic. Comment *k* uses pharmaceutical products to illustrate the relevant characteristics of an "unavoidably unsafe" product; it does not define an "unavoidably unsafe" product as a pharmaceutical product. Perhaps the relevant characteristics of an "unavoidably unsafe" product effectively limit comment *k* to pharmaceutical products. That conclusion, though, should be based upon analysis rather than being assumed. To interpret comment *k*, we need to identify the reasons why some products like the rabies vaccine ought to be exempt from strict liability.

Mark A. Geistfeld, PRINCIPLES OF PRODUCTS LIABILITY 75-76 (2006).

The rationale for comment *k* is most easily illustrated by cases involving blood contaminated by a virus, such as hepatitis, that was not detectable at the time of sale. According to Justice Roger Traynor of the California Supreme Court, blood is a "classic example" of an "unavoidably unsafe product" under comment *k*. Roger Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 Tenn. L. Rev. 363, 367 (1965). "[L]ike contaminated blood, Pasteur Vaccine [discussed in comment *k*] is impure, and its use may have adverse consequences which

cannot be predicted or avoided." *Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 124 (Col. 1983).

Consider a case involving the defendant blood bank's sale of blood contaminated by a virus that was unknown at the time of sale. The presence of such a virus in the blood constitutes a construction or manufacturing defect because it is a departure from the "design" or specification for the blood. *Cf.* Restatement (Third) of Torts: Products Liability § 2 cmt. c ("[A] manufacturing defect is a departure from a product unit's design specifications."). As in a case of contaminated food, the seller of contaminated blood can be subject to strict liability regardless of whether the virus could have been discovered by the exercise of reasonable care. *See, e.g., Cunningham v. MacNeal Mem'l Hosp.*, 266 N.E.2d 897, 903 (Ill. 1970) ("[W]e believe that whether or not defendant can, even theoretically, ascertain the existence of serum hepatitis virus in whole blood employed by it for transfusion purposes is of absolutely no moment. Any other ruling would be entirely inconsistent with the concept of strict tort liability."), *overruled by statute*, 745 Ill. Comp. Stat. Ann. 4012, enacted in 1971; *see also* Jay M. Zitter, *Liability of blood supplier for injury or death resulting from blood transfusion*, 24 A.L.R.4th 508, § 2[a] (1983) ("[I]n several blood transfusion cases wherein injury or death resulted from blood which was contaminated with serum hepatitis, a theory was asserted that since the blood was impure and unfit for its intended uses, the blood bank in the sale of the blood had breached an implied warranty under a sales act or the Uniform Commercial Code, or should be held liable under strict liability in tort for the sale of an unreasonably dangerous product.").

The application of strict liability in these cases would result in blood suppliers facing liability, even though the blood was sold in a state that was safe as possible at that time. The effect of liability in such cases would not have made the blood supply more safe, but rather would have disrupted the provision of blood and caused a substantial loss of social value.

In one case, for example,

> the experts for both sides all agreed that in December 1966 (when the blood was transfused) there was no known scientific or medical test for determining whether blood drawn from a donor contained serum hepatitis virus. Further, Dr. Robert Goodman, a pathologist and medical director of County Blood Bank, testified that as of that date the overall incidence of transfusion hepatitis was "about 1.3 in a hundred cases transfused" and that "the carrier rate, the people who remain with residual virus after infection, is five percent."

Brody v. Overlook Hosp., 317 A.2d 392, 395 (N.J. App. Div. 1974), *aff'd*, 332 A.2d 596 (N.J. 1975). Based on these facts, a blood supplier ordinarily would incur strict liability for hepatitis injuries for every one consumer out of a 100, an amount that vastly exceeds the liabilities typically generated by construction or manufacturing defects (such as the occasional bottle of soda that explodes).

The potential scope of strict liability for blood suppliers was then substantially increased by the AIDS epidemic. The first AIDS diagnosis occurred in 1981, and so any tests or warnings regarding the virus were not feasible for all blood products sold prior to then. "By this time, however, a large number of he-

mophiliacs had become infected. The plaintiffs have presented evidence that 2,000 hemophiliacs have died of AIDS and that half or more of the remaining U.S. hemophiliac population of 20,000 may be HIV-positive." *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1296 (7th Cir. 1995). Liability for these injuries would "hurl the industry into bankruptcy." *Id.* at 1300.

The problem of contaminated blood accordingly reveals the underlying principle of comment *k*. Holding suppliers liable for contaminated blood, even though it was impossible to make the blood more safe, might have led to the pernicious effect of decreasing the supply of blood with no concomitant gains in safety.

> A higher risk of injury, coupled with a social concern for bankruptcy rooted in the requirements of public health and safety, differentiates blood and other pharmaceutical products from the vast majority of other products. These characteristics justify the exemption of a product from strict liability under comment *k* of the *Restatement (Second)*, much like a highly risky activity with significant social value is exempted from the *Restatement (Second)* rule of strict liability for abnormally dangerous activities. [Restatement (Second) of Torts § 520(f)].

Geistfeld, *supra*, at 78-79.

Recognizing the problem, virtually all state legislatures have responded by adopting statutes that immunize blood suppliers from strict liability. *See* Restatement (Third) of Torts: Products Liability § 19 cmt. c ("Absent a special rule dealing with human blood and tissue, such contamination presumably

would be subject to the rule[of strict liability for a construction defect].... However, legislation in almost all jurisdictions limits the liability of sellers of human blood and human tissue to the failure to exercise reasonable care, often by providing that human blood and human tissue are not 'products' or that their provision is a 'service' [and therefore not subject to strict *products* liability]."). In justifying the exemption, courts and legislatures have often expressed concern about the way in which strict liability could have a potentially disruptive effect on the supply of blood. *See, e.g., Zichichi v. Middlesex Mem'l Hosp.*, 528 A.2d 805, 810 (Conn. 1987).

In cases not governed by these statutes, courts have reached the same outcome by applying comment *k* to the sale of blood products containing an undetectable virus at the time of sale that would otherwise constitute a defect subject to strict liability. *See, e.g., Rogers v. Miles Labs., Inc.*, 802 P.2d 1346, 1352 (Wash. 1991) ("Numerous other jurisdictions are in accord with our decision not to apply the theory of strict liability to suppliers of blood and manufacturers of blood products") (citations omitted); *Miles Labs., Inc. v. Doe*, 556 A.2d 1107, 1121 (Md. 1989); *Belle Bonfils Mem'l Blood Bank*, 665 P.2d at 121; Restatement (Third) of Torts: Products Liability § 19 cmt. c ("Where legislation has not addressed the problem, courts have concluded that strict liability is inappropriate for harm caused by such product contamination."). *But see Cunningham*, 266 N.E.2d at 903 (applying strict liability to sale of blood contaminated by a virus that was not reasonably detectable at the time of sale).

Thus, comment *k* is based on a safety principle that exempts a performance-based defect from strict lia-

bility when the product furthers the public interest in health and safety and is "unavoidably unsafe." The imposition of strict liability would not make the product safer—it is "unavoidably unsafe"—and could result in a socially problematic safety outcome by disrupting the supply of a product that furthers the public interest in health and safety. In cases of this type, application of strict liability would be contrary to the safety rationale for strict products liability, justifying the limitation of strict liability embodied in comment *k*. *See, e.g.*, *Belle Bonfils Mem'l Blood Bank*, 665 P.2d at 124 ("[T]he *raison d'etre* of strict liability is to force some hazardous products out of the market. The same rationale does not apply to blood or *vaccines* which are life-saving and *which have no known substitutes.*") (emphasis added); *Miles Labs.*, 556 A.2d at 1121 ("[T]he fundamental purpose underlying the theory of strict tort liability is to force hazardous products from the market.").

III. Comment *k* Does Not Bar Design Defect Claims Based on a Reasonable Alternative Design of the Vaccine That Reduces Risk of Side Effects

Properly interpreted, comment *k* bars certain claims of strict products liability in which the defect is defined solely in terms of product performance. For example, the Sabin oral polio vaccine uses an attenuated or weakened form of the viral agent to immunize the recipient, which in turn can cause vaccine-associated paralytic polio in either recipients or close contacts. In these cases, the design or formulation of the vaccine causes it to perform in a self-defeating manner, the paradigmatic example of a product malfunction that typically subjects the product seller to strict liability. *See, e.g.*, *Grinnell v.*

Charles Pfizer & Co., 274 Cal. App. 2d 424, 433 (Cal. App. 1969) ("it is clearly the law in California that the theory of strict liability in tort is availab[illegible] in cases where the vaccinated individual contracts the disease the vaccine was designed to protect against"); *see also, e.g., Allison v. Merck & Co.*, 878 P.2d 948, 952 (Nev. 1994) (holding that a measles, mumps and rubella vaccine "malfunctioned" and was subject to strict liability because an unavoidable side effect allegedly caused plaintiffs' son to suffer blindness, deafness and mental retardation). Such a claim of strict liability is barred by comment *k* when the vaccine is "prepared properly" in conformance with state of the art quality control and is accompanied by a proper warning. *See, e.g., Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1323-24 (Kan. 1986) (applying comment *k* to a Sabin-type vaccine and concluding as a matter of law that an unavoidable side effect of the vaccine is not "a manufacturing or design defect").

When a vaccine is "unavoidably unsafe" under comment *k*, strict liability would not lead to a safer vaccine but instead could create the unsafe outcome in which liability reduces the supply and use of the vaccine within society. Comment *k* thus applies only when there is no safety rationale for liability. Consequently, it does not bar negligence liability, which necessarily targets unreasonably dangerous products in order to promote tort law's safety objective. *Compare* Restatement (Second) of Torts § 402A cmt. a ("The rule [of strict liability] stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved.") *with id.* § 395 cmt. f (adopting rule of negligence liability for product

design without any reference to drugs, vaccines or comment *k*).

To be sure, negligence liability could threaten the financial viability of a drug or vaccine manufacturer. Comment *k*, however, does not insulate the seller of an unreasonably dangerous product from the threat of bankruptcy. Comment *k* expressly contemplates liability for inadequate or defective warnings, and negligence liability for such warnings can be extensive, as illustrated by the asbestos cases. *See, e.g.*, *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973) (applying Texas law) (upholding jury verdict finding that defendants failure to warn of asbestos hazards was subject to both negligence and strict products liability).

For these reasons, comment *k* does not prevent plaintiffs from establishing liability for defective design by proving that a vaccine or drug has a reasonable alternative design.

> The proof of defect shows that risk was avoidable, establishing that the product was not "unavoidably unsafe." The exemption from liability afforded by comment *k* turns out to be no different than the exemption afforded by the requirement of defect—an "unavoidably unsafe" product must not be capable of being reasonably redesigned and is not subject to liability for that reason alone. In these cases, comment *k* does not expressly provide for an independent limitation of liability justifying the special treatment of pharmaceutical products.

Geistfeld, *supra*, at 124; *see also* Henderson & Twerski, 77 Cornell L. Rev. at 1540 (arguing that the history of comment *k* shows that it "is simply unten-

able" to conclude that "comment *k* sought to establish sophisticated rules governing judicial review of conscious *drug* design choices").

This interpretation of comment *k* was not considered by the Court of Appeals in the present suit. The court assumed that a case-by-case application of comment *k* regarding defective design would eliminate any preclusive effect whatsoever: "If we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court." *Bruesewitz*, 561 F.3d at 246. Because the Vaccine Act most plausibly provides at least some limitation of liability for defective design, the Court of Appeals concluded that the Act must preempt all claims of defective design. *Id.*

Properly interpreted, comment *k* only bars design and manufacturing defect claims based on product malfunctions involving unavoidable side effects, a limitation of liability permitting design claims alleging that the vaccine is not "unavoidably unsafe" because there is a reasonable alternative design that would reduce the risk in question. Based on comment *k*, the Vaccine Act does not preclude claims of the type brought by petitioners in the present case.

CONCLUSION

The judgment of the Court of Appeals should be reversed.

Respectfully submitted.

MARK A. GEISTFELD
Counsel of Record
New York University School of Law
40 Washington Square S.
New York, New York 10012
(212) 998-6683

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AMICUS CURIAE BRIEF

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In the
Supreme Court of the United States

RUSSELL BRUESEWITZ, ET AL.

Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETH-AYERST LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF GLAXOSMITHKLINE LLC, MERCK SHARP & DOHME CORP. (FORMERLY KNOWN AS MERCK & CO., INC.), AND SANOFI PASTEUR INC. AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

PAUL D. CLEMENT
Counsel of Record
DARYL JOSEFFER
CANDICE CHIU
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, DC 20006
(202) 737-0500
pclement@kslaw.com

Counsel for Amicus Curiae GlaxoSmithKline LLC

July 30, 2010

* additional counsel listed on inside cover

Additional Counsel:

DINO S. SANGIAMO
DAVID S. GRAY
VENABLE LLP
750 E. Pratt Street
Baltimore, MD 21202
(410) 244-7400
Counsel for Amicus Curiae Merck Sharp & Dohme Corp. (formerly known as Merck & Co., Inc.)

M. DIANE OWENS
BRADLEY S. WOLFF
SWIFT, CURRIE, MCGHEE & HIERS, LLP
1355 Peachtree Street, NE, Suite 300
Atlanta, GA 30309
(404) 874-8800
Counsel for Amicus Curiae Sanofi Pasteur Inc.

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BRIEF OF GLAXOSMITHKLINE LLC, MERCK SHARP & DOHME CORP. (FORMERLY KNOWN AS MERCK & CO., INC.), AND SANOFI PASTEUR INC. AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

INTERESTS OF THE *AMICI CURIAE* [1]

Along with respondent Wyeth, Inc., *amici curiae* GlaxoSmithKline LLC ("GSK"), Merck Sharp & Dohme Corp. (formerly known as Merck & Co., Inc.) ("Merck"), and Sanofi Pasteur Inc. ("Sanofi") are the remaining major childhood vaccine companies supplying vaccines for use in the United States. *Amici* have lived through this high-stakes debate before—in 1986, when Congress enacted the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 *et seq.* ("Vaccine Act" or "Act"). Congress passed the Act in part to protect the vaccine supply by shielding vaccine companies from tort suits like this one, while at the same time establishing a generous federal compensation system for the injured.

A decision by this Court to reverse the Third Circuit's preemption holding would upend the

[1] Pursuant to this Court's Rule 37.6, *amici* state that no counsel for any party authored this brief in whole or in part, and that no person or entity other than *amici* or their counsel made a monetary contribution to the preparation or submission of this brief. The parties have consented to the filing of this brief, and letters evidencing such consent have been filed with the Clerk of this Court, pursuant to this Court's Rule 37.3.

status quo that has persisted since the 1986 Act. It would unravel Congress's targeted effort in that Act to limit the extreme liability exposure that was driving large numbers of vaccine companies out of the U.S. market. *Amici* therefore have an interest in making sure this Court understands why Congress determined that allowing courts across the nation applying a patchwork of different state-law standards to second-guess vaccine designs — and saddling vaccine companies with the costs of design-defect claims — would contribute to further attrition in the number of companies selling vaccines in the United States. The expanded liability exposure petitioners seek would exacerbate unique challenges of the vaccine industry and threaten the vaccine supply.

INTRODUCTION AND SUMMARY OF ARGUMENT

The vaccine industry is unique in a number of important respects. Vaccines, by all accounts, are one of the great public health successes in medical history. And because of the importance of vaccines in preventing epidemics that could affect many thousands if not millions of people, the vaccine companies have a singularly close and interdependent relationship with government agencies.

But history has shown that vaccine companies are also quite vulnerable to the economic pressures that result from high research, development, and manufacturing costs, the lessened profit potential that comes from selling vaccines primarily to governmental entities and a public that under-

values their often unseen benefits, and the susceptibility to tort suits that results from selling a product that does not treat an existing illness but is designed for administration to apparently healthy children.

As respondent's brief explains, petitioners' attempt to subject vaccine companies to case-by-case, state-law design defect claims would effect a radical change in the status quo and defy the text of the Vaccine Act. *See* Resp. Br. at 29-45. Far from contemplating that vaccine companies would be subject to design-defect liability, § 22(b)(1) of the Vaccine Act expressly preempts state-law tort claims with only two specific carve-outs, for manufacturing defect and failure-to-warn claims. That preemption is a crucial element of Congress's carefully crafted balance, which protects vaccine manufacturers against destabilizing tort liability while also establishing a generous and streamlined administrative compensation scheme.

This brief details the far-reaching implications of petitioners' position. Design-defect liability would re-inject the very costs and uncertainties that pushed vaccine companies out of the market in the 1970s and 1980s — a trend § 22(b)(1) was specifically designed to arrest. Congress was alarmed by the fact that many vaccine companies were leaving the market. Indeed, many important vaccines are now supplied by only one or two companies. And the nation has had to grapple with serious supply shortages of numerous vaccines.

The dwindling number of vaccine companies reflects the unique economic pressures such companies face from higher development and

manufacturing costs and lower revenues relative to many other types of pharmaceutical products. Liability pressures from meritless tort suits are also unusually great for the vaccine industry. When an apparently healthy child begins to show symptoms of a disease or condition shortly after being vaccinated, parents and jurors are naturally inclined to blame the vaccine. *Post hoc ergo propter hoc* is a logical fallacy, but when the manifestation of an illness follows a vaccination, the impulse to sue can be strong. While jurors see a sick child who was apparently healthy before receiving the vaccine, they do not see the enormous benefits of vaccines — for both the people who take them and the population at large, which benefits from controlling the spread of infectious diseases.

Litigation concerning the preservative thimerosal, which gave rise to the related petition for certiorari in *American Home Products Corporation v. Ferrari* (No. 08-1120), provides an excellent example of how thousands of suits can be filed notwithstanding an overwhelming consensus in the scientific community that has resoundingly rejected the theory underlying the suits. In fact, multiple studies by a number of researchers involving a variety of methodologies have been thoroughly analyzed by the Institute of Medicine of the National Academy of Sciences, which concluded that the "evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." Institute of Medicine, Immunization Safety Review Committee, *Immunization Safety Review: Vaccines and Autism* 7 (2004) ("*Immunization Safety Review*") (emphasis omitted). Other blue-ribbon scientific panels,

including the World Health Organization Strategic Advisory Group of Experts, have reached similar conclusions.

By replacing tort suits with the Vaccine Act's generous compensation system, Congress sought to "free manufacturers from ... uncertain tort liability, and thereby ... keep manufacturers in the market." *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994) (Breyer, C.J.). Opening up a new front of design-defect liability would ignore that intent.

Design-defect tort suits are especially unwarranted because of the federal government's unique role with respect to vaccines. All childhood vaccines subject to the Vaccine Act's preemption provision and compensation scheme are recommended for childhood use by the Department of Health and Human Services ("HHS"). HHS plays an active role in the research, development, and ongoing monitoring and evaluation of the safety of vaccines, even apart from the Food and Drug Administration's ("FDA") rigorous licensing process. The government, moreover, is the largest purchaser of childhood vaccines in the United States, overseeing the nationwide Vaccines For Children Program, which distributes free vaccines to children who might not otherwise be vaccinated because of inability to pay. Through that comprehensive program, Congress charged expert federal agencies, not state courts, with determining which vaccines should be administered. And Congress protected the interests of any injured persons with a generous and fair administrative compensation system.

There is no good reason to upset Congress's balance, ignore the lessons and practice of the past 24 years, and thrust the vaccine industry back into uncertainty.

ARGUMENT

I. CONGRESS ENACTED § 22(B)(1) OF THE VACCINE ACT IN PART BECAUSE THE VACCINE INDUSTRY'S UNIQUE ECONOMIC CHALLENGES, INCLUDING SUSCEPTIBILITY TO TORT SUITS, ENDANGERED PUBLIC HEALTH BY DRIVING VACCINE COMPANIES OUT OF THE MARKET.

A. The Number Of Vaccine Companies Was Precipitously Declining When Congress Enacted § 22(b)(1).

In pushing for a new frontier of design-defect liability for the vaccine industry, petitioners ignore the acute economic pressures on that industry. But Congress did not ignore the pressures, which threatened the vaccine supply. Those economic pressures, which are formidable and pose unique public health concerns, were a pivotal force behind Congress's enactment of the Vaccine Act generally and § 22(b)(1) in particular. When Congress enacted the Act in 1986, vaccine manufacturers were exiting the U.S. market, raising serious concerns about the fragile state of the industry. Limiting all but two types of tort claims against vaccine companies, and channeling claims to a specialized "Vaccine Court," was a key centerpiece of Congress's comprehensive effort to stem that tide

and stabilize the market. *See* H.R. Rep. No. 99-908, pt. 1, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344 (describing the "instability and unpredictability of the childhood vaccine market" as an "overriding concern"); *Schafer*, 20 F.3d at 4 (Breyer, C.J.) (Act sought to "free manufacturers from ... uncertain tort liability, and thereby ... keep manufacturers in the market").

Maintaining financial incentives to develop vaccines remains as critical a public health priority today as it was in 1986. The public relies heavily on manufacturers to produce new and improved vaccines in sufficient supplies, even as the number of vaccine manufacturers supplying the U.S. market has dwindled. The historical trend is stark: 1949 opened the "golden age of vaccine development." Stanley Plotkin et al., *Vaccines* 7 (5th ed. 2008). For two decades, scientists like Jonas Salk, Albert Sabin, and others made groundbreaking discoveries of inoculations for polio, flu, measles, mumps, and rubella, among other infectious diseases. There were 26 companies producing vaccines in 1967. By 1977, however, half the commercial vaccine manufacturers had stopped producing and distributing vaccines. *See* Institute of Medicine, *Financing Vaccines in the 21st Century: Assuring Access and Availability* 121 (2003) ("IOM Report"). By 1985, only four commercial firms were producing and distributing the primary vaccines used in compulsory vaccination programs. Subcomm. on Health and Env't, *Childhood Immunizations: A Report*, 99th Cong. 72 (1986).

Today, Wyeth, GSK, Merck, and Sanofi are among a handful of companies that sell childhood vaccines domestically. Most troubling, there remain only one or two domestic manufacturers of several critical vaccines, including the measles, mumps, and rubella ("MMR") vaccine. *See* IOM Report, at 122.

Number Of Producers of Select Childhood Vaccines For The U.S. Market, 2010

Vaccine	No. Of Producers
Diphtheria, Tetanus, Pertussis	2
Hepatitis A	2
Hepatitis B	2
Inactivated Poliovirus (IPV) (stand-alone)	1
Measles, Mumps, Rubella	1
Meningococcal	2
Pneumococcal	1
Rotavirus	2
Varicella (chickenpox)	1

See FDA, *Complete List of Vaccines Licensed for Immunization and Distribution in the US*, http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.

Meanwhile, the nation has grappled with serious shortages in vaccine supply. Since 1998, nine of twelve routinely recommended childhood vaccines have been plagued by shortages. *See* John K. Inglehart, *Financing Vaccines: In Search of Solutions That Work*, Health Affairs vol. 24(3), at 594 (2005). From 2000 to 2002 alone, there were nationwide shortages of five childhood vaccines. *See* IOM Report, at 131-32. The Centers for Disease Control ("CDC") have publicly attributed the shortages, in part, to "companies leaving the vaccine market." CDC, *Current Vaccine Shortages*

& *Delays*, http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm#chart.

As Congress determined in enacting the Vaccine Act, the "withdrawal of even a single vaccine manufacturer" from the childhood vaccine market could pose serious scarcity problems. H.R. Rep. No. 99-908, at 6-7. The prospect of fewer vaccinations not only risks disease for the unvaccinated, but also creates conditions in which disease can spread freely throughout communities. The resurgence of childhood diseases that current vaccines have largely, if not wholly, brought under control is a very real possibility if any more vaccine companies exit the market. *See id.* (manufacturer withdrawals risk "a resurgence of preventable diseases"); World Health Organization ("WHO"), *Vaccinations in Disaster Situations*, http://new.paho.org/disasters/index.php?option=com_content&task=view&id=554&Itemid=664 (reduced vaccine coverage risks resurgence of "diseases that have already been controlled and/or eradicated"). In a system operating at maximum capacity, interruptions to vaccine production or shortages could place domestic immunization programs in jeopardy.

B. Vaccine Companies Face Daunting And Unique Economic Pressures.

The economic challenges facing the vaccine industry are daunting and distinct. Prohibitive research, development, and manufacturing expenses, pricing constraints, and tort liability all pose serious hurdles to profitability and have contributed to the dramatic decline in the domestic

vaccine industry. The strain of those economic pressures would only be exacerbated if the Court were to saddle vaccine companies with a new front of design-defect liability.

From concept to licensing, the vaccine development process is costly, risky, and protracted. The manufacturing process is also tightly controlled and expensive. Unlike other pharmaceuticals, which may be produced through relatively standardized chemical engineering processes, vaccine development and manufacturing are highly unpredictable. *See* IOM Report, at 109. Due to the complexity of biologics, most vaccine candidates fail in pre-clinical or early clinical development. Few new vaccines are licensed annually. Even a company that invests $100 million per year on research and development can expect to turn around a new product only once every 6 to 8 years. *See* Plotkin et al., *Vaccines*, at 38.

Merely manufacturing an approved vaccine is a capital-intensive and lengthy endeavor. Manufacturing plants for vaccines require $50 to $300 million investments, depending on their size and complexity; the plants also require something on the order of an additional 20% expenditure for cleaning and process validation. *See id.* Beyond the capital involved, vaccine companies typically must commit to building a manufacturing plant 4 to 6 years before the expected licensing stage in order to minimize the time lag between licensing and product launch. *Id.*

Many manufacturing processes, moreover, are not scaleable. *See id.* The processes often entail "complex transformation of live biologic organisms" and require "[h]ighly sterile, temperature controlled environments ... at each manufacturing step." IOM Report, at 109. The Institute of Medicine has estimated that 60% of vaccine manufacturing costs are fixed production costs associated with quality assurance, administrative labor, and other manufacturing overhead — and therefore not impacted or alleviated by changes in volume. *Id.* at 114. And because FDA-approved vaccines must undergo a rigid batch inspection process, it is difficult for companies to achieve cost efficiencies through process improvements. *See id.* at 109, 116.

The costs of new vaccine development have soared accordingly. Estimates indicate that research-and-development costs for vaccines rose over three-fold from $231 million in 1991 to $802 million in 2003. *See* Plotkin, et al., *Vaccines*, at 38.

The revenues from vaccine sales, however, have "remained relatively constant," making the recoupment of research, development, and manufacturing costs a continuous challenge. IOM Report, at 116. The revenue potential is constrained by the limited number of vaccinations required over a lifetime. Most vaccines are taken one to four times over a lifetime, whereas many prescription drugs are administered to patients for many years. *See id.*

Bulk purchases by federal and state governments further depress prices. The CDC is

the largest purchaser and distributor of vaccines in the nation. *Id.* at 119. Over half of all childhood vaccines manufactured for U.S. sales are bought by state and local public health departments through CDC contracts. *See* Margaret S. Coleman, et al., *Factors Affecting U.S. Manufacturers' Decisions To Produce Vaccines*, Health Affairs vol. 24(3), at 636 (2005). Accordingly, the CDC has leverage to negotiate deep discounts. Historically, the federal government has received discounts of 40-50% below list price. *See* IOM Report, at 128.

The government has also imposed price caps on certain vaccines. In 1993, for example, Congress enacted the Childhood Immunization Initiative, which guaranteed free vaccines to all eligible children and limited price increases on government contracts to the rate of inflation. *See* 42 U.S.C. §§ 1396s(a)(1)(A), 1396s(d)(3)(B). The government has other means of exerting control over vaccine prices as well; the Veterans Administration, for instance, imposes penalties on companies that increase prices for non-government customers beyond the consumer price index. IOM Report, at 130-31.

In turn, those governmental initiatives foster public expectations for low-cost vaccines, further driving prices downward. The irony is that vaccines' great success in eliminating preventable diseases has reduced the perceived threat of those diseases and led to undervaluation of vaccines generally. *See* Robert Giffin, et al., *Childhood Vaccine Finance And Safety Issues*, Health Affairs vol. 23(5), at 105 (2004) ("as vaccine-preventable

diseases decrease in response to vaccines, the benefits of vaccination recede from public memory"). The "unwillingness to pay can be traced to consumers as well as to institutional purchasers." *Prologue: Vaccine Financing and Economics*, Health Affairs vol. 24(3), at 652 (2005). These economic pressures have led manufacturers to shy away from the vaccine industry altogether, halt production of certain vaccines, or otherwise shift resources. *See* Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, Health Affairs vol. 24(3), at 628 (2005).

All these economic strains reached a boiling point in the "product liability crisis" of the 1980s — the backdrop for Congress's enactment of the Vaccine Act. *See* IOM Report, at 131. Vaccine companies faced unprecedented exposure to tort liability, culminating in a rash of market departures and vaccine supply shortages. In 1985 alone, 219 lawsuits were filed against vaccine manufacturers seeking over three billion dollars in damages for injuries alleged to have been caused by diphtheria-tetanus-pertussis ("DTP") vaccines — a figure over 30 times greater than the market value of all DTP vaccine sales that year. *See* Gary L. Freed, et al., *Safety of Vaccinations*, J. Am. Med. Ass'n vol. 276(23), at 1869-72 (1996); Alan R. Hinman, *DTP Vaccine Litigation*, Am. J. Dis. Child. vol. 140(6), at 528-30 (1986). Many of these DTP lawsuits involved design-defect claims. *See* Resp. Br. 7-8. In 1986, a single suit attributing a boy's paralysis to Lederle's pertussis vaccine culminated, despite a lack of scientific evidence, in a jury award of $1.13 million. *See Toner v. Lederle Labs.*, 779

F.2d 1429 (9th Cir. 1986). That figure was "equivalent to more than half of the entire pertussis vaccine market." Offit, Health Affairs vol. 24(3), at 622-30.

Vaccine manufacturers took notice. In 1984, Wyeth announced that it had ceased production of its DTP vaccine due to the "extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance." *Vaccine Injury Compensation*, Hearings on H.R. 556 before Subcomm. on Health and Env't, 98th Cong. (1984), at 295 (statement of Dr. Daniel L. Shaw, Jr., Wyeth Vice President of Medical Affairs). That same year, Connaught Laboratories Inc., a predecessor in interest of Sanofi Pasteur, temporarily withdrew from the vaccine market as it sought to clarify its product liability insurance coverage. *Id.* at 266 (statement of Dr. James Mason, CDC Director). And Lederle publicly questioned whether it would stay in the vaccine business as costs of litigation continued to rise. *Id.* at 239 (statement of Robert D. Johnson, Lederle President).

In enacting the Vaccine Act, Congress sought to protect the vaccine supply by bringing litigation exposure under control. Petitioners make the startling claim that Congress "heard and rejected" the argument that tort liability would cause "vaccine manufacturers [to] exit the market" and destabilize the industry. Pet. Br. at 58. Congress heard the argument all right, but certainly did not reject it. Instead, Congress described the "*instability and unpredictability of the childhood vaccine market*" as being one of its "two overriding

concerns" in enacting the Vaccine Act. H.R. Rep. No. 99-908, at 7 (emphasis added). Congress thus fully recognized the fragility of the vaccine industry and knew that the "withdrawal of even a single manufacturer" could exacerbate vaccine shortages and the resurgence of preventable diseases. *Id.* Congress accordingly crafted the Vaccine Act to "free manufacturers from ... uncertain tort liability, and thereby ... keep manufacturers in the market." *Schafer*, 20 F.3d at 4 (emphasis added); *see also* Offit, Health Affairs vol. 24(3), at 627 ("the [National Vaccine Injury Compensation Program] was a model system to prevent abuses by personal injury lawyers").

To that end, Congress barred civil actions arising from alleged vaccine-related injuries unless first presented to the Office of Special Masters of the U.S. Court of Federal Claims ("Vaccine Court"). Section 22(b)(1) also barred all but two liability theories — manufacturing defect and failure-to-warn — and created a presumption, in any elective civil suit filed after exhaustion of the administrative remedy, that FDA-approved vaccine warnings are adequate if the manufacturers complied with federal approval and labeling laws. *See* 42 U.S.C. § 300aa-22(b)(2). Congress also prevented States from eliminating those two avenues of liability. *Id.* § 300aa-22(e). And, of course, Congress established a generous, no-fault compensation program — under which the Vaccine Court has paid out billions of dollars. By enacting all these related provisions, Congress struck a deliberate balance that it hoped would keep vaccine manufacturers in the market. That balance has

prevailed for nearly a quarter century. To now permit plaintiffs to seek state-law tort remedies on "design-defect" claims would fundamentally upend that balance. And it would thwart Congress's intent by risking the very attrition of vaccine companies and corresponding endangerment of the vaccine supply that Congress sought to prevent.

II. VACCINE COMPANIES FACE UNIQUE AND EXTREME LIABILITY EXPOSURE.

A. The Nature Of Vaccine-Related Injuries Creates Distinct Susceptibilities To Tort Litigation Regardless of Fault.

Vaccine companies are uniquely susceptible to tort litigation, even when the liability theory is not supported by science. This heightened exposure stems from the singular nature of what are thought to be vaccine-related injuries.

Unlike other pharmaceuticals, vaccines are usually administered to apparently healthy individuals. *Cf.* Pet. Br. at 3. When an apparently healthy child experiences a serious condition in the wake of vaccination, parents naturally have the instinct to search for something to blame. Vaccines, administered to millions of children each year on a mandatory basis for school entry and participation in day care, frequently fit the bill. When the injured child manifests an injury soon after being vaccinated, the impulse to bring suit against the vaccine company is extraordinarily and understandably strong — even though many diseases and developmental disorders naturally

and independently manifest themselves during childhood, coincidentally during the same time period vaccines are administered.

When confronted with a child who appeared previously healthy but is now suffering after being vaccinated, it is difficult for a state court, as opposed to a federal regulatory agency, to comprehend the benefits of the vaccine as a whole. The benefits of vaccination tend to dissipate from public memory whereas the risks loom front and center. As vaccines have eliminated diseases like smallpox and polio in the United States and wiped away the terror of those scourges, the "very success of vaccines leads some to question their necessity." Giffin, et al., Health Affairs vol. 23(5), at 105.

The "spectacularly effective" success of vaccines, however, redounds as much to society as to any individual. H.R. Rep. No. 99-908, at 4. Vaccination is instrumental to the public health. Vaccines not only inoculate individuals against specific diseases that they might otherwise contract, but they protect the entire population against the spread of infection, including contagious diseases that could otherwise become debilitating and devastating epidemics. *See id.* at 2 ("Use of vaccines has prevented thousands of children's deaths each year and has substantially reduced the effects resulting from disease."). As Congress recognized, vaccines are crucial to the health of both the vaccinated and non-vaccinated, notwithstanding any risk that biologic products may pose to certain individuals. *See id.* And in any event, serious adverse reactions to vaccines are extremely rare. That very

"extension of perspective from individuals to their communities is the business of public health." Plotkin et al., *Vaccines*, at 1573. Nonetheless, that broader perspective of a vaccine's impact on public health is unlikely to have much impact on any parent. The injury to the specific child, no matter how many nameless others were benefitted, is all the parents see.

Notably, the Vaccine Act's compensation scheme applies only to vaccines that the government has recommended for all children. *See* 42 U.S.C. § 300aa-14. The government has thus made an affirmative judgment as to each vaccine that its minimal and unlikely risks are justified by its greater good — protecting the vulnerable childhood population as a whole from potentially debilitating infectious diseases. At the same time, the government has also established a separate compensation system for those individuals who have been truly injured by a vaccine and can demonstrate a causal relationship between the injury and vaccination. Courts applying state law are poorly situated to second-guess and undo that calculus.

In any event, petitioners' position would open up an entire enterprise of second-guessing. To state courts, alternative designs may appear "safer" even when the scientific evidence does not support such a conclusion. Further, in many instances, theoretically "safer" alternatives may prove to be less efficacious. *See, e.g.*, Justin Gillis, *Safer Smallpox Vaccines in Works: U.S. Preparing for Potential Bioterror Attack*, Wash. Post, Nov. 14,

2005, at A1 (modified vaccine developed in Germany "essentially trades potency for safety").

Petitioners nonetheless argue, as a policy matter, that vaccine companies *should* be subject to vaccine-related injury claims whenever plaintiffs can claim that another vaccine design is allegedly safer than the one approved by FDA. In their view, subjecting vaccine companies to state tort liability would "incentiviz[e] manufacturers to design vaccines to prevent avoidable side effects." Pet. Br. at 51.

In reality, history has exposed the fragility of the vaccine industry and the attendant dangers of that instability. Petitioners' proposal to alter the status quo that has prevailed for nearly 25 years would ignore that history. Vaccine companies would face the new burden of defending against speculative allegations that safer alternatives were available in courts across the country. And vaccine companies would find themselves facing the real possibility that state courts would find that they ought to have distributed a vaccine that the FDA did not — and would not — license.

B. The Thimerosal Litigation Confirms That The Risk of Substantial Litigation Is Far From Hypothetical.

The state of thimerosal litigation, which gave rise to the related petition for certiorari in *American Home Products Corporation v. Ferrari* (No. 08-1120), amply demonstrates that litigation fears in this case are real. Thimerosal was developed in the late 1920s as a preservative to

prevent the growth of potentially life-threatening microbial contaminants in vaccines, such as bacteria and fungi, and was used extensively from 1930 on. It prevents serious adverse effects such as the staphylococcus infection that killed 12 of 21 children inoculated with a diphtheria vaccine that lacked a preservative in 1928. Unlike other vaccine preservatives used at the time, thimerosal does not tend to reduce the potency of the vaccines that it protects. *See* Jeffrey P. Baker, *Mercury, Vaccines, and Autism*, Am. J. Pub. Health vol. 98(2), at 244-53 (2008).

Allegations linking thimerosal to the onset of autism erupted in the early 2000s. Every government public health agency and reputable scientific body to address the question has rejected the hypothesis that thimerosal-containing pediatric vaccines ever caused or contributed to autism. These include the Institute of Medicine of the National Academy of Sciences, the World Health Organization, the U.S. Centers for Disease Control and Prevention, the American Academy of Pediatrics, the U.K. Committee on the Safety of Medicines, and the European Agency for the Evaluation of Medicinal Products.[2] As of 2008, at

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[2] *See, e.g.*, Immunization Safety Review Committee, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* (2004); WHO, *Statement on Thiomersal* (Aug. 2003), http://www.who.int/vaccine_safety/topics/thiomersal/statement200308/en/print.html; WHO, *Position of the Global Advisory Committee on Vaccine Safety regarding concerns raised by recent paper about the safety of thiomersal-containing vaccines* (May 2003), http://www.who.int/vaccine_safety/topics/thiomersal/statement/en/print.html; European Agency for the

least eight major studies had examined the effect of reductions or removal of thimerosal as a preservative from vaccines, and all demonstrated that autism rates failed to decline despite the removal of thimerosal. The most notable scientific analysis of the literature, undertaken by a panel of world-renowned experts appointed by the Institute of Medicine, decisively concluded that "the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." *Immunization Safety Review*, at 7.

Nonetheless, between 1999 and 2009, *5,600* claims relating to autism were filed in the Vaccine Court. *See* Health Resources & Services Administration, *National Vaccine Injury Compensation Program Statistics Report* (July 14, 2010) ("*Statistics Report*"), http://www.hrsa.gov/vaccinecompensation/statistics_report.htm. Of that figure, approximately 718 cases have been concluded without compensation, with the vast

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Evaluation of Medicinal Products, *Public Statement on Thiomersal in Vaccines for Human Use* (Mar. 2004), www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500003904; U.K. Committee on Safety of Medicines, *Further Data Support Safety of Thiomersal in Vaccines* (Feb. 2003), http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON2015721; CDC, *Thimerosal & Vaccines*, http://www.cdc.gov/flu/about/qa/thimerosal.htm; American Academy of Pediatrics, *What Parents Should Know About Thimerosal, available at* http://www.aap.org/immunization/families/ingredients.html#thimerosal; American Academy of Pediatrics, *Study Fails To Show A Connection Between Thimerosal And Autism* (2003).

majority of remaining cases pending. *Id.* In February 2009, the Vaccine Court issued opinions in three test cases finding that there was no proof of causation supporting the claimants' theory that a combination of thimerosal with the MMR vaccine could cause autism.[3] In March 2010, the Vaccine Court ruled in another three test cases that thimerosal-containing vaccines do not cause autism.[4]

Approximately 5,000 claims, however, are still pending in the Omnibus Autism Proceeding before the Vaccine Court. *See Statistics Report*; *accord* U.S. Br. in *Am. Home Prods. Corp. v. Ferrari*, No. 08-1120 (U.S. Mar. 5, 2009), at 5, 17. Over 350 civil actions have been filed against vaccine manufacturers in various courts across the country alleging that childhood vaccines cause autism. And in October 2008, in *American Home Products Corporation v. Ferrari*, the Georgia Supreme Court construed the preemptive scope of the Vaccine Act

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[3] *See Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *9-11 n.16 (Fed. Cl. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 603 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

[4] *See Mead ex rel. Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Mar. 12, 2010); *King ex rel. King v. Sec'y of Health & Human Servs.*, No. 03-548V, 2010 WL 892296 (Fed. Cl. Mar. 12, 2010); *Duyer ex rel. Duyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Mar. 12, 2010).

narrowly and paved the way for a suit against manufacturers alleging that a child suffered neurological injuries from exposure to FDA-approved vaccines containing thimerosal.

As the thimerosal litigation demonstrates, the possibility of potentially destabilizing litigation is not a mere matter of speculation should the Court reject preemption. The potential flood sits behind a temporary dam in the Vaccine Court — and the consequence of construing § 22(b)(1) not to preempt such claims would be dramatic. The scientific community has uniformly rejected these claims. But that will not prevent the thousands of claimants who have already filed in Vaccine Court (and the others who have already filed in court) from seeking a contrary conclusion from a jury. The costs of fighting these suits, even if none results in a finding of liability, would be daunting for an industry Congress sought to preserve and foster.

The thimerosal story highlights the particular susceptibility of vaccine companies to tort suits — regardless of their scientific merits — simply because a wide variety of illnesses happen to manifest themselves in early childhood at the time when children are vaccinated. *See* FDA, *VAERS Overview*, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/Overview/default.htm. While some of those suits may be brought under manufacturing defect or failure-to-warn theories, history teaches that design-defect claims — that invite juries to reconsider whether a vaccine should

ever have been approved by regulatory authorities — pose the greatest threat to the industry's viability. Unleashing design-defect claims attacking, for example, the use of thimerosal despite the lack of any reliable scientific evidence for such claims, would hardly incentivize vaccine manufacturers to produce safer products. Rather, it would risk the needless withdrawal of safe and effective products from the marketplace and could bury vaccine companies in ever-greater litigation costs.

III. CONGRESS SUBJECTED VACCINE DESIGN TO A DETAILED FEDERAL REGULATORY SCHEME THAT IS ILL-SERVED BY STATE TORT CLAIMS.

Petitioners strain to downplay federal regulation of vaccines and to brandish design-defect liability as the solution to some purported regulatory gap. *See* Pet. Br. at 27, 54-56. But petitioners' portrayal of vaccine regulation as lax and deficient does not square with reality. The federal regulatory scheme governing vaccines is almost unparalleled in its detail and depth.

Precisely because vaccines have been "one of the most spectacularly effective public health initiatives this country has ever undertaken," H.R. Rep. No. 99-908, at 4, the government has made safe vaccines a critical priority. The CDC is the single largest purchaser and distributor of vaccines in the United States. *See* IOM Report, at 119. The National Institutes of Health ("NIH") fund one-third of all vaccine research funding. *Id.* And FDA oversees a comprehensive regulatory process

specifically "designed to foster safe and effective products." *Id.* at 121. Far from dis-incentivizing careful design and condoning misconduct, federal agencies and officials exercise comprehensive control over vaccine design from both the supply and the demand sides. *See generally* U.S. Br. in *Am. Home Prods. Corp. v. Ferrari*, at 12-15.

First and foremost, all childhood vaccines subject to the Vaccine Act's compensation program have been recommended by HHS (through the CDC) for administration to all children. *See* 42 U.S.C. § 300aa-14; CDC, *2010 Child & Adolescent Immunization Schedules*, http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm. Thus, as to each vaccine, HHS has made an affirmative judgment that vaccination will advance the health of the population as a whole, and that the Vaccine Act's generous, no-fault compensation program will be available to address any potential adverse reactions among certain individuals. Not only does the government play an active role in funding, developing, and monitoring vaccine products, it affirmatively creates the obligation that communities be vaccinated at the outset.

The government's proactive role in vaccine development and administration is underscored by the HHS Secretary's responsibility for "*mak[ing] or assur[ing] improvements* in ... labeling, warning, [and] use instructions ... and research on vaccines, in order to *reduce the risk* of adverse reactions to vaccines." 42 U.S.C. § 300aa-27(a)(2) (emphases added). The Secretary is further required, under the Vaccine Act, to "establish a task force on safer

childhood vaccines" to make recommendations as to vaccine safety and effectiveness. *Id.* § 300aa-27(b). And the statute additionally charges the Secretary with promoting the development and refinement of safer childhood vaccines with "fewer and less serious adverse reactions than those vaccines on the market on December 28, 1987." *Id.* § 300aa-27(a)(1). That statutory mandate to affirmatively develop safer products has no equivalent in the prescription drug or medical device context.

Indeed, many safe vaccines have been the product of collaborative partnerships between the public and private sectors. Manufacturers have, in conjunction with federal agencies, developed at least twenty childhood vaccines since 1986 — including vaccines for influenza, hepatitis A, and meningococcus. *See* Resp. Br. at 28, 53. And nearly $1.5 billion of vaccine research funding annually comes from the NIH. *See* NIH, *Estimates of Funding for Various Research, Condition, and Disease Categories* (published Feb. 1, 2010), http://report.nih.gov/rcdc/categories/.

Each vaccine subject to the Vaccine Act, moreover, has undergone and is continuing to undergo a comprehensive FDA licensure process. The FDA puts biologics through a pre-market approval system set forth in section 351 of the Public Health Service Act, 42 U.S.C. 262(a). That rigorous licensure process focuses on whether the biologics are "safe, pure, and potent." *Id.* § 262(a)(2)(C); *see also* 21 C.F.R. § 601.2 (describing detailed requirements for biologics licensing applications). "New childhood vaccines in

particular are put through some of the most exhaustive examinations and largest clinical trials of any FDA-approved product." U.S. Br. in *Am. Home Prods. Corp. v. Ferrari*, at 14. Each potential manufacturer must likewise obtain a license from the FDA and submit sample batches of the vaccine and summaries of tests they have undertaken on the relevant batches to the agency. *See* 21 C.F.R. §§ 601.1, 601.2. The FDA thus examines not only the safety and effectiveness of the vaccine, but also the production facilities and processes, including employee training and work conditions. *See id.* §§ 211.25, 600.10.

Petitioners' attempts to paint the government as "lack[ing] the resources and tools" to monitor vaccine safety thus fundamentally understate the extent of the government's role. Pet. Br. at 55. The Vaccine Act provides precisely the incentives to "improve the safety of ... products" that petitioners assert must come from state law. *Id.* at 54.

Indeed, the federal agencies assume a *continuous* monitoring role over vaccine production and distribution: FDA has authority to inspect manufacturing plants of licensed products to evaluate production processes and compliance with good manufacturing processes and to test products for purity, potency, and the absence of contaminants. *See* Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure, and Stress*, Health Affairs vol. 24(3), at 603 (2005). FDA, moreover, may issue vaccine recalls if there are safety or effectiveness problems. *See id.*

There is also an elaborate and distinct system in place for monitoring adverse events associated with vaccines. FDA thoroughly reviews adverse event reports and use instructions to evaluate whether the information given to health care providers "'adequately warn[s]" them of any dangers. FDA, *Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information*, at 2-3 (Sept. 2004) (quoting 42 U.S.C. § 300aa-1 note), http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074845.htm. FDA independently reviews scientific literature worldwide and typically recommends labeling revisions if "new information on a vaccine's safety and efficacy becomes available after licensure" and FDA concludes that the labels do not reflect currently available information. *Id.* at 1, 3.

At the same time, the Vaccine Act requires manufacturers themselves to report any adverse side effects or contraindicating reactions to the government through the Vaccine Adverse Event Reporting System ("VAERS"). 42 U.S.C. § 300aa-25(b). Notably, while there exist analogs to that system in non-vaccine contexts, adverse event reporting requirements are "even more comprehensive" for vaccines than for drugs and other biological products. U.S. Br. in *Am. Home Prods. Corp. v. Ferrari*, at 15; *compare* 42 U.S.C. § 300aa-25(b) (vaccines), *with* 21 C.F.R. § 600.80 (biological products generally), 21 U.S.C. § 355(k)(1) (drugs), and 21 C.F.R. § 314.80 (drugs). Meanwhile, the Vaccine Safety Datalink ("VSD"),

administered by the CDC, aggregates vaccination and exposure data from eight managed care organizations. That database facilitates focused studies — for example, of the rates of adverse events among persons who have received or not received specific vaccines -- as well as the detection of less common adverse reactions than those that may emerge from clinical trials. *See* Inter-Agency Vaccine Group, *A Comprehensive Review of Federal Vaccine Safety Programs and Public Health Activities*, at 18 (Dec. 2008), http://www.hhs.gov/nvpo/nvac/subgroups/vaccinesafety.html#vaccine (last visited July 30, 2010). There is no analog to the VSD for drugs. *See* Resp. Br. at 14.

In sum, from funding and development through manufacturing and monitoring of vaccines, federal agencies have a uniquely prominent role. Far from lacking or ineffectual, the government's web of vaccine regulations surpasses its rigorous oversight responsibilities in other pharmaceutical contexts. *Compare Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008). Indeed, the stringency of costs of compliance with vaccine regulation have historically been a major factor behind manufacturers' decisions to exit the market. *See* IOM Report, at 122 ("Another reason for exit arises when the costs of ... regulatory compliance are too great to support more than one producer"); Offit, Health Affairs vol. 24(3), at 626 ("added financial burden of now disproving rare adverse events before licensure is another disincentive to making vaccines").

Congress clearly believed that the Vaccine Act struck the correct balance between state and federal law. Congress did so by including not one, but two, provisions addressing the relationship of federal and state law. As demonstrated, design-defect claims were preempted, but Congress deliberately carved out manufacturing defect and failure-to-warn claims. As to those preserved theories of liability, Congress went further and prevented States from eliminating liability. *See* 42 U.S.C. § 300aa-22(e) ("No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part"). The preserved claims complemented the regime by ensuring that approved vaccines were properly manufactured and giving manufacturers an incentive to follow the FDA's labeling. *See id.* § 300aa-22(b)(2) (vaccines "presumed to be accompanied by proper directions and warnings" if manufacturer complied with FDCA requirements and FDA licensure provisions).

Congress, when it enacted the Vaccine Act, did not intend for courts applying a patchwork of state laws to assess which vaccines are "unavoidably unsafe," apart from vaccines that are improperly manufactured or accompanied by inadequate warnings. Rather, Congress squarely allocated that function to government agencies. It is state courts, not the government, that "lack[] the resources and tools" to evaluate vaccine safety. Pet. Br. at 55. Rather than aid the Vaccine Court process, allowing plaintiffs to seek tort remedies

under state law for design defects would plainly circumvent that process and thwart the national public health policy founded upon the use of federally approved vaccines. Case-by-case, design-defect liability exposure under state law would not, as petitioners claim, "complement[]" or "promote" federal regulation of vaccines. *Id.* at 54-55. It would directly undermine it, in direct contravention of what Congress intended when enacting the Vaccine Act.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals for the Third Circuit should be affirmed.

Respectfully submitted,

Paul D. Clement
Daryl Joseffer
Candice Chiu
KING & SPALDING LLP
1700 Pennsylvania Ave., NW
Washington, DC 20006
(202) 737-0500
Counsel for Amicus Curiae GlaxoSmithKline LLC

Dino S. Sangiamo
David S. Gray
VENABLE LLP
750 E. Pratt Street
Baltimore, MD 21202
(410) 244-7400
Counsel for Amicus Curiae Merck Sharp & Dohme Corp. (formerly known as Merck & Co., Inc.)

M. Diane Owens
Bradley S. Wolff
SWIFT, CURRIE, MCGHEE & HIERS, LLP
1355 Peachtree Street, NE,
Suite 300
Atlanta, GA 30309
(404) 874-8800
Counsel for Amicus Curiae Sanofi Pasteur Inc.

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AMICUS CURIAE BRIEF

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No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ, *et al.*,

Petitioners,

v.

WYETH, INC., fka WYETH LABORATORIES, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF *AMICI CURIAE* NATIONAL VACCINE INFORMATION CENTER, ITS CO-FOUNDERS AND 24 OTHER ORGANIZATIONS IN SUPPORT OF PETITIONERS

MARY S. HOLLAND
245 Sullivan Street
New York, NY 10012
(212) 998-6212

ROBERT J. KRAKOW
Counsel of Record
1205 Franklin Avenue
Suite 110
Garden City, NY 11530
(516) 354-3300
rkrakow@me.com

Counsel for Amici Curiae
National Vaccine Information Center, its Co-Founders
and 24 Other Organizations

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 (Act) precludes liability for certain claims against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1).

The question presented is: does Section 22(b)(1) preclude all vaccine design-defect claims even if the vaccine's side effects were avoidable?

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the parent advocates who helped draft the Act, §§ 300aa-1 *et seq*, and twenty five organizations. They respectfully submit this brief in support of Petitioners. It is a matter of national importance that the judiciary interprets and applies the Act as Congress intended.[1] A list of *amici* is available at Exhibit A.

Amicus curiae the National Vaccine Information Center (NVIC), founded in 1982 by parents whose children were injured or died following DPT vaccination, is widely recognized as the oldest, largest and most effective non-profit national organization advocating for the institution of vaccine safety and informed consent protections in U.S. public health programs. NVIC has assisted thousands of individuals who have suffered serious health problems, hospitalizations, injuries and deaths following vaccination. It promotes scientific research to evaluate vaccine safety and defends the ethical principle of informed consent for medical interventions, including vaccination, which carry a risk of injury or death.

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae*, or its counsel, made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and such consents have been lodged with the Clerk.

Amici curiae Jeffrey Schwartz, Barbara Loe Fisher and Kathi Williams, former members of Dissatisfied Parents Together (DPT) and co-founders of NVIC, were the leading parent advocates in negotiating and drafting the Act. From 1973-79, Mr. Schwartz was Environmental Counsel for the House of Representatives Health and Environment Subcommittee of the Energy and Commerce Committee, the Subcommittee and Committee that drafted the Act. Ms. Fisher is President and Ms. Williams is Vice-President of NVIC.

Amici curiae the International Medical Council on Vaccination, the Center for Personal Rights, the New Jersey Coalition for Vaccination Choice and the New York Alliance for Vaccination Choice advocate for the right to free and informed vaccination choices.

Amicus curiae the National Gulf War Resource Center promotes the health and welfare of U.S. military veterans and their families and focuses on environmental toxins and the safety of vaccines. *Amicus curiae* Veterans for Common Sense advocates for veterans. It focuses on public health and safety for Gulf War veterans, and in particular on vaccine safety.

Amici curiae the Elizabeth Birt Center for Autism Law and Advocacy, Autism One, Generation Rescue, the Autism Trust USA, the *Autism File* magazine, the *Age of Autism* daily web newspaper, the *Schafer Autism Report*, the National Autism

Association (NAA), the Autism Action Network, and Talk About Curing Autism (TACA) are organizations that serve individuals and families affected by autism and other neurological disorders.

Amici curiae The Coalition for Safe Minds (Sensible Action for Ending Mercury-Induced Neurological Disorders), NoMercury, the Coalition for Mercury-Free Drugs and the Alan D. Clark, M.D. Memorial Research Foundation are organizations which investigate and raise awareness about the risks of exposure to mercury from medical products, including mercury in vaccines.

Amicus curiae Truth About Gardasil provides information and assistance to families about the human papillomavirus vaccine. *Amicus curiae* the Pandemic Response Project seeks to reform emergency health laws to allow citizens to make free and informed decisions.

Amicus curiae the National Economic and Social Rights Initiative promotes a human rights vision for the United States that ensures dignity and access to the basic resources needed for human development and civic participation, including healthcare. *Amicus curiae* Citizens for Health advocates citizens' rights to make natural health choices.

SUMMARY OF ARGUMENT

Hannah Bruesewitz was a healthy infant until she received a diphtheria, tetanus and pertussis (DPT) vaccine in 1995. Soon after vaccination, she suffered catastrophic injuries and now endures a lifelong residual seizure disorder. Her condition requires extraordinary care and financial resources. Hannah's family sought compensation under the Act but the compensation program denied her recovery. She then proceeded to trial court to argue that the DPT vaccine she received was defectively designed and that her injuries should have been avoided through use of a known, safer alternative. The court granted summary judgment against her, deciding that Section 22(b)(1) of the Act preempted all vaccine design defect claims. The Third Circuit affirmed the federal district court's decision to grant summary judgment. Fourteen years after Hannah's injury, she has yet to find justice.

The primary purpose of the Act is to compensate children. The Act created a compensation system as an alternative to the tort system, not a substitute.

Parents of vaccine-injured children stood up for their children's rights in drafting the Act and do so now in asking this Court to reverse the Third Circuit's decision to bar all design defect claims from civil court. The Act is a compromise that has created a compensation system and granted some liability protection to vaccine manufacturers. But that liability protection is not blanket immunity. Section

22 of the Act protects vaccine manufacturers from liability in a civil action "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."

The plain meaning and legislative history of the Act do not support preemption of all design defect claims. Indeed the parent *amici* who helped craft the Act would never have agreed to such preemption.

Unfortunately, the compensation program is not working as Congress intended. The program rejects most petitioners, as it did Hannah. Health and Human Services has failed to maintain and update the presumptions for injury that would allow the system to succeed. Given the compensation system's inadequacy, keeping the courthouse doors open, as Congress intended, is more important than ever.

This Court's precedents, the Act's plain meaning and its legislative history support reversal of the Third Circuit's decision below.

ARGUMENT

I. THE PURPOSE OF THE ACT IS TO COMPENSATE VACCINE-INJURED CHILDREN, NOT TO IMMUNIZE MANUFACTURERS FROM LIABILITY FOR ALL DESIGN DEFECTS.

The House Committee on Energy and Commerce (Committee), which drafted the Act in 1986, created the Vaccine Injury Compensation Program (Compensation Program or vaccine court) as an alternative to the tort litigation system, not its replacement. The tort system was neither compensating the children that vaccines injured nor ensuring a reliable vaccine supply. Tort litigation was costly, time consuming and usually undercompensated or failed to compensate victims. H.R. Rep. No. 99-908, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347. The threats of litigation to vaccine manufacturers and grossly insufficient compensation to the vaccine-injured risked the vaccine program itself. *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994) (citations omitted). *See also Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007). Congress created the Act to generously compensate vaccine victims, to ensure the vaccine supply and improve vaccine safety.

The legislators who drafted the Act understood that this carefully crafted scheme would fail without the support of parents whose children

had already suffered vaccine injuries. As Barbara Loe Fisher recently explained:

> The young parents of vaccine injured children, who came to the table in the early 1980s at the request of congressional staff to fight for the rights of vaccine consumers and the vaccine injured, agreed to work on the Act because of promises made by Congress and the American Academy of Pediatrics (AAP) that the proposed legislation would provide a fair, expedited, non-adversarial, less traumatic, less expensive no-fault compensation alternative to civil litigation. We believed we were participating in the development of a law which would give – in the words of the then AAP Chairman – "simple justice to children."

Statement to the Advisory Commission on Childhood Vaccines (Nov. 18, 2008), (Fisher Statement) http://www.nvic.org/injury-compensation/vaccineinjury.aspx.

These parents, organized initially as Dissatisfied Parents Together (DPT), educated Congress and the public about vaccine injuries and the need for a no-fault compensation system. They worked for nearly five years, through multiple drafts and congressional hearings, to reach a workable

compromise. At first, vaccine manufacturers and physician organizations advocated that an administrative no-fault system be victims' exclusive remedy. But parents insisted on the right to go to court after first filing in the compensation system if it was too slow, provided too little compensation or if victims wished to bring common law claims. The parents also insisted that the Act contain provisions to make vaccines safer, so that fewer children would be harmed in the future. *See generally,* Nitin Shah, *When Injury is Unavoidable: The Vaccine Act's Limited Preemption of Design Defect Claims*, 96 Va. L. Rev. 199 (2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1407343n; Division of Health Promotion and Disease Prevention, National Research Council, *Vaccine Supply and Innovation*, 183-92 (National Academies Press, 1985); Harris L. Coulter & Barbara L. Fisher, *A Shot in the Dark* 213-14 (Harcourt Brace Jovanovich, 1985); James Colgrove, *State of Immunity: The Politics of Vaccination in Twentieth-Century America*, 213-17 (University of California Press, 2006). As Dr. Martin H. Smith, AAP's past President wrote, "it became evident that working together with this group [DPT] was well advised and necessary." Martin H. Smith, *National Childhood Vaccine Injury Compensation Act*, 82 Pediatrics 264, 266 (1988).

After long, hard years of negotiation, Congress passed the Act in 1986. The Committee's report (1986 Report) accompanying the Act includes a section-by-section analysis of its provisions. Section 13 of the Act makes clear that the Compensation

Program does not require petitioners to prove that the vaccine was defective or that the injury was avoidable. Rather, vaccine court would presume causation based on certain criteria, such as a temporal relationship between vaccination and symptoms specified in a "Vaccine Injury Table."

The Committee acknowledged the consequences of this presumption, intending to compensate even when the causal relationship was tenuous:

> The Committee...recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related ....[T]he Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

H.R. Rep. 99-908 at 8-35, *reprinted in* 1986 U.S.C.C.A.N. at 6349-76.

The Table's purpose was to ensure that the compensation process would remain administrative rather than litigious. If the Vaccine Injury Table contains a particular presumptive vaccine injury, the burden of proof shifts to respondent HHS to demonstrate that the injury was "unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B).

For "off-table" injuries, a claimant must show that the vaccine more likely than not caused the injury. § 300aa-13. The Act also contemplates that the Secretary of HHS should add new vaccine injuries to the Table as new vaccines are mandated. H.R. Rep. 99-908, *reprinted in* 1986 U.S.C.C.A.N. at 6361.

Like in all compromises, no stakeholder in the negotiations got everything it wanted. Parents were forced to accept substantial limitations in the administrative system – mandatory filing, capped damages, no juries and limits on discovery. Manufacturers and physician groups were forced to accept that the administrative system would not be victims' exclusive remedy. And to get the deal done, Congress was forced to pass the Act without funding it. H.R. Rep. No. 100-391(I) (1987) *reprinted in* 1987 U.S.C.C.A.N. 2313-1. As AAP President Dr. Smith wrote in 1988 to his member pediatricians, "[t]his was the best compromise settlement...that could be reached." Smith at 268.

Several statements at the time the Act passed suggest that Congress recognized that victims, who had duly filed in the Compensation Program, could take design defect claims to court under Section 22(b). When presenting the Act to the full House of Representatives for a vote, Rep. Henry Waxman, the Act's chief sponsor, stated that civil claims for "inadequately researched" vaccines would be preserved under Section 22. *National Childhood Vaccine Injury Act of 1986*, 99th Cong. Rec. 30760 (1986) (statement of Rep. Henry A. Waxman). *See also* Henry A. Waxman, *When a Vaccine Injures a*

Child: A No-Fault Way to Compensate, Wash. Post, Oct. 9, 1986, at A27. Rep. Waxman's description of this claim, that a vaccine's design did not take adequate account of avoidable safety risks, would likely be a design defect. *See* Shah at 34.

Furthermore, the Committee explicitly rejected the opportunity to create a broad exemption for all design defect claims when it considered the Act. Proposals were considered by the Committee that would have explicitly preempted all design defect claims, but the final version did not contain those provisions. H.R. Rep. 100-391(I), at 691 (1987), *as reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365. By rejecting language that would have barred all design defect claims, Congress showed its intent to permit courts to decide on a case-by-case which side effects were genuinely "unavoidable." Moreover, the Committee emphasized in its 1987 Report when it authorized funding that it had not decided, as a matter of law, which, if any, vaccines were unavoidably unsafe: "This question is left to the *courts* to determine in accordance with applicable law." *Id.* (emphasis added).

The legislative history suggests that all the stakeholders – Congress, parents, manufacturers and physicians – understood that victims preserved the right to take design defect claims to court. Respondent and its *amici* appear to be trying to achieve through the judiciary what they failed to obtain through Congress.

A. Congress Intended to Streamline Victims' Rights, Not Eliminate Them.

Parent advocates Schwartz, Fisher and Williams did not, and would not, have supported the Act if they thought that executive agencies or federal courts would later interpret it to foreclose access to a civil court remedy for design defect. They argued that because children face compulsory vaccination in order to attend school, their access to justice in the event of injury must be robust and must include design defect claims that manufacturers could have feasibly avoided.

They pointed to past court cases of vaccine design defects to demonstrate the need to preserve this type of claim. They referenced *Griffin v. United States*, in which the U.S. government was held liable because the Division of Biologics Standards of the National Institutes of Health released a batch of Sabin polio vaccine that did not conform to its own regulatory standards (the manufacturer settled), 351 F. Supp. 10 (E.D. Pa. 1972), *aff'd in part, rev'd in part and remanded*, 500 F.2d 1059 (3d Cir. 1974). And they also pointed to four cases in which manufacturers of quadrivalent vaccine (diphtheria, tetanus, pertussis, and poliomyelitis) were held liable because a new preservative activated the pertussis component. *Tinnerhold v. Parke Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd* 411 F.2d 48 (2d Cir. 1969), *Stromsodt v. Parke Davis & Co.*, 257 F. Supp. 991 (D.N.D. 1966), *aff'd* 411 F.2d 1390 (8th Cir. 1969), *Vincent v. Thompson*, 361 N.Y.S.2d 282 (Sup. Ct. 1974), *rev'd in part*, 377 N.Y.S.2d 118

(App. Div. 2d Dep't 1975), and *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727 (2d Cir. 1979) (finding that plaintiff had introduced enough evidence to go to the jury on the issues of product defect or proximate causation against defendant manufacturer Quadrigen). *See also Vaccine Supply and Innovation* at 86.

The Act and its legislative history simply do not make sense without the understanding that the tort system remains an available alternative for such cases. And Congress' intent to keep the courthouse doors open is even more important today than it was in 1986.

B. The Compensation Program Is Not Working as Congress Intended, Making Recourse to Civil Court More Critical Than Ever.

Although Congress enacted the Act more than twenty years ago, the Compensation Program is not functioning as Congress intended. Already in 1999, Barbara Loe Fisher testified before Congress about why parents of vaccine-injured children were dissatisfied:

> There is bitter disappointment and pervasive unhappiness among parents...with the current structure and administration of the vaccine injury compensation program....[W]hen parents are unable to obtain financial assistance to care for a severely vaccine

> injured children, public faith in the mass vaccination system is further eroded.

Fisher Statement.

Parents of vaccine-injured children perceive vaccine court to be mean-spirited and hostile towards plaintiffs, experts and attorneys. Parents believe that vaccine court has a conflict of interests between protecting the vaccine program and compensating those injured by it. They observe that vaccine court will "protect the reputation of the current vaccine system at all costs – even if it means denying compensation to vaccine victims." *Id.* Vaccine court simply has not fulfilled its mission to compensate vaccine injury victims like Hannah Bruesewitz.

The overwhelming majority of cases in vaccine court today are "off-table," unable to take advantage of presumptive causation and thus require costly and time-consuming causation hearings, are highly adversarial, and end without compensation.[2] The recent Omnibus Autism Proceeding, aggregating almost 5,000 claims of vaccine-induced autism, has no place in the statutory scheme Congress laid out for individual determinations of vaccine injury. *Cedillo v. Secretary of HHS*, 2009 WL 331968 (Fed.

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[2] *See* National Vaccine Injury Compensation Program, Statistic Report (May 31, 2010) available at http://www.hrsa.gov/vaccinecompensation/statistics_report.htm showing that as of May 5, 2010, 13,357 petitions have been filed and 2,443 have been compensated, or approximately 18%.

Cl. 2009); *Hazlehurst v. Secretary of HHS*, 2009 WL 332306 (Fed. Cl. 2009); *Snyder v. Secretary of HHS*, 2009 WL 332044 (Fed. Cl. 2009); *see also* Gordon Shemin, Comment, *Mercury Rising: The Omnibus Autism Proceeding and What Families Should Know Before Rushing Out of Vaccine Court*, 58 Am. U. L.Rev. 459, 484-90 (2008).

Furthermore, HHS has not expanded presumptions for recovery, as the 1986 Report recommended. H.R. Rep. 99-908 at 19-20, *reprinted in* 1986 U.S.C.C.A.N. at 6360-61. While the Centers for Disease Control and Prevention now recommend 46 doses of nine new vaccines for children,[3] "no new signs, symptoms or injuries have been added to the Table of Injuries...– except anaphylaxis within four hours for the hepatitis B vaccine." Fisher Statement. In other words, HHS has not updated the Vaccine Injury Table's presumptions to correspond to today's substantially increased vaccine schedule.

Had the Bruesewitz family filed its initial claim one month earlier in 1995, Hannah's residual seizure disorder presumptively would have been

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[3] Department of Health and Human Services, Centers for Disease Control and Prevention, Recommended Immunization Schedule for Persons 0 through 6 Years and 7 Through 18 Years (May 31, 2010) *available at* http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#printable, indicating nine new compulsory vaccines added since 1986: hepatitis B, rotavirus, *haemophilus influenzae* type b, pneumococcal, influenza, varicella, hepatitis A, meningococcal, human papillomavirus. Those that existed before 1986 were diphtheria, tetanus, pertussis, measles, mumps, rubella and inactivated poliovirus.

compensated. However, in an administrative sleight of hand, HHS removed this presumption from the Vaccine Injury Table in March, 1995, forcing Hannah Bruesewitz and similar DPT-injured children to prove causation. 60 Fed. Reg. 7678 (Feb. 8, 1995); *see also Andreu v. Secretary of HHS*, 569 F.3d 1367, 1374 (2009). Fourteen years of litigation later, Hannah Bruesewitz has yet to receive one penny in federal compensation for vaccine injury.

By Congress' measure, vaccine court has failed. In its 1986 Report, the Committee wrote:

> The entire [vaccine court] proceeding...is to take place as expeditiously as possible and, in no case, should take more than one year....[W]ithout such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner.

H.R. Rep. 99-908, at 17, *reprinted in* 1986 U.S.C.C.A.N. at 6358. *See also Compensating Vaccine Injuries: Are Reforms Needed?: Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources*, 106th Cong. (1999). It was to prevent the sort of injustice that Hannah Bruesewitz has suffered that Congress left petitioners free to reject the Compensation Program's findings "and go on to court." H.R. Rep. 99-908, at 12, *reprinted in* 1986 U.S.C.C.A.N. at 6353.

II. IN *BRUESEWITZ*, THE THIRD CIRCUIT ELIMINATED RIGHTS THAT CONGRESS EXPRESSLY PROTECTED.

While Congress wanted the Compensation Program to divert litigation from the traditional civil tort system, it never bestowed blanket immunity on vaccine manufacturers from all design defect claims. Congress preempted only those tort claims for "unavoidably unsafe" vaccines. Section 22(b)(1) states:

> [n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death ... if the injury or death resulted from side effects that were *unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

§ 300aa-22(b)(1) (emphasis added).

Congress explicitly imported the "unavoidable" language from comment k to § 402A of the Restatement (Second) of Torts, which applies only to "products which, in the present state of human knowledge, are quite incapable of being made safe." Restatement (Second) of Torts § 402A cmt. k (1965). To read Section 22 as preempting all design defect claims would effectively read the word "unavoidable" out of the statute. As Justices O'Connor and Breyer stated in a concurrence to an earlier case under this Act:

> [t]o the extent possible, we adhere to 'the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative. The construction adopted by the Court of Appeals contravenes this principle.

Shalala v. Whitecotton, 514 U.S. 268, 278 (1995) (O'Connor, J., concurring) (citations omitted).

Furthermore, Congress has subsequently authorized statutes, such as the Pandemic Preparedness Act, 42. U.S.C. § 247d-6d, for epidemic products that explicitly preempt all state laws that otherwise might apply. By contrast, the Act expressly preempts *state* statutes that prohibit civil actions against manufacturers for vaccine-related injuries. 42 U.S.C. § 300aa-22(e). Thus Congress was not silent on preemption of state tort remedies; the Act affirmatively preserved state contract and tort remedies even in cases where states tried to extinguish them on their own.

The plain meaning and legislative history of the Act suggest only one plausible reading of § 22(b)(1): that manufacturers are free from liability for design defects if the injury that a victim suffered was "unavoidable."

This is the conclusion that two Circuit Courts of Appeal have previously reached. The Fourth Circuit in *Abbot v. Am. Cyanimid Co.*, 844 F.2d 1108 (4th Cir. 1988), held that federal law did not foreclose a

plaintiff's defective design claims under Virginia law, even if an adequate warning was present. And the Fifth Circuit similarly found no preemption of state liability law for vaccine manufacturers. *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988). They reasoned that Congress intended for petitioners to be able to determine which vaccine side effects were unavoidable on a case-by-case basis under state common law.

There is nothing in the Act that prohibits vaccine-injured plaintiffs from putting design defect questions before a jury, so long as they meet all other substantive and procedural requirements. And other thresholds remain high in design defect cases, such as the requirements for putting scientific evidence before a jury.[4] But parents of vaccine-injured children believed then, and now, that the tort system provides a critical check to ensure that vaccines on the market are "the safest and most effective vaccines possible." 1986 Report, Part C.

A. The Third Circuit's Decision in *Bruesewitz* Departs From This Court's Precedent on Preemption.

The Court's recent decision in *Wyeth v. Levine*, reaffirming the long-standing presumption against federal preemption, bolsters the conclusion

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[4] *See* Shah at 42, citing thimerosal cases in federal and state courts where defendant-manufacturers have succeeded in having courts dismiss plaintiffs' claims under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) and *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) standards of evidence before trial on grounds of scientific implausibility.

that the Third Circuit failed to follow this Court's precedent. 129 S. Ct. 1187, 1194 (2009) (quoting *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996)). Earlier, in *Altria Group v. Good*, the Court explained that

> [this] assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States....Thus, when the text of a preemption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors preemption.

129 S. Ct. 538, 543 (2008) (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). Absent explicit language barring design defect claims, the Third Circuit should have allowed Hannah Bruesewitz her day in court.

The Georgia Supreme Court in *American Home Products v. Ferrari* unanimously held that § 22 of the Act does not preempt all design defect claims, but only those side effects that were unavoidable. 284 Ga. 384, 386 (2008). Applying *Bates* to resolve the ambiguity in § 22, the *Ferrari* court opined that "[I]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed its intent more clearly." 284 Ga. at 393. The *Ferrari* court looked carefully at Congress' intent, expressed in the Act and in the 1987 amendments to fund the program. It wrote:

> We hesitate to hold that a manufacturer is excused from making changes it knows will improve its product merely because an older, more dangerous version received FDA approval....[To do so] "would 'have the perverse effect of granting complete [tort] immunity from design defect liability to an entire industry'."

284 Ga. at 394 (citations omitted).

To square *Bruesewitz* with the Court's preemption decisions, the Court should find the Act does not imply preemption. The Act permits petitioners to bring design defect claims to court, and manufacturers may then rebut those claims by showing that any injuries from its design were unavoidable.

This Court should reverse the Third Circuit's decision that rewrites the agreement that Congress, parents, manufacturers and physicians painstakingly reached in 1986.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment below.

Robert J. Krakow
1205 Franklin Ave., Suite 110
Garden City, NY 11530
(516) 354-3300

Mary S. Holland
245 Sullivan St.
New York, NY 10012
(212) 998-6212

Counsel for *Amici Curiae*

June 1, 2010

EXHIBIT

EXHIBIT A

Age of Autism (www.ageofautism.com)

Alan D. Clark, M.D. Memorial Research Foundation

Autism Action Network (www.autismactioncoalition.org)

Autism File USA (www.autismfile.com)

AutismOne (www.autismone.org)

Autism Trust USA (www.theautismtrust.com)

Center for Personal Rights (www.americanpersonalrights.org)

Citizens for Health (www.citizens.org)

Coalition for Mercury-Free Medicine (http.mercury-freedrugs.org)

The Coalition for Safe Minds (www.safeminds.org)

Elizabeth Birt Center for Autism Law and Advocacy (www.autismone.org, click EBCALA)

Generation Rescue (www.generationrescue.org)
International Medical Council on Vaccination
(http.imcv.info)

National Autism Association
(www.nationalautismassociation.org)

National Economic and Social Rights Initiative
(www.nesri.org)

National Gulf War Resource Center
(www.ngwrc.org)

National Vaccine Information Center
(www.nvic.org)

New Jersey Coalition for Vaccination Choice
(http.njvaccinationchoice.org)

New York Alliance for Vaccination Choice
(www.nyavc.com)

NoMercury

Pandemic Response Project
(www.pandemicresponseproject.com)

Schafer Autism Report (www.sarnet.org)

Talk About Curing Autism
(www.talkaboutcuringautism.org)

Truth About Gardasil (www.truthaboutgardasil.org)

Veterans for Common Sense
(www.veteransforcommonsense.org)

AMICUS CURIAE BRIEF

No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ, ET AL.,
Petitioners,

v.

WYETH, INC.,
Respondent.

ON WRIT OF CERTIORARI
TO THE SUPREME COURT OF VERMONT

BRIEF OF *AMICI CURIAE* KENNETH W. STARR AND ERWIN CHEMERINSKY IN SUPPORT OF PETITIONERS URGING REVERSAL

MICHAEL R. HUGO
277 Dartmouth St.
Boston, MA 02116
(617) 448-4888

JONATHAN S. MASSEY
Counsel of Record
MASSEY & GAIL, LLP
1325 G St. NW, Suite 500
Washington, D.C. 20005
(202) 652-4511

June 2010

BATEMAN & SLADE, INC BOSTON, MASSACHUSETTS

QUESTION PRESENTED

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 expressly preempts certain design defect claims against vaccine manufacturers "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

The Question Presented is:

Whether the Third Circuit erred in holding that, contrary to its plain text and the decisions of this Court and others, Section 22(b)(1) preempts all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not?

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Erwin Chemerinsky, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES (Aspen Law & Business 3d ed. 2006) 2

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INTEREST OF *AMICI CURIAE*

Amici Kenneth W. Starr and Erwin Chemerinsky are scholars who teach and write about federal preemption of state law, as well as practitioners with extensive experience in the field of preemption.[1]

Kenneth W. Starr is a former Judge of the U.S. Court of Appeals for the District of Columbia (1983-1989) and Solicitor General of the United States (1989-1993). He has served as Dean of the Pepperdine University School of Law and, as of June 2010, will become the fourteenth president of Baylor University. He has written widely on federal preemption issues.[2]

Erwin Chemerinsky is the current and founding dean of the University of California, Irvine School of Law. He has taught at the DePaul College of Law (1980–83), University of Southern California Law School (1983–2004), Duke School of Law (2004–

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[1] This brief has been filed with the written consent of the parties, which is on file with the Clerk of Court. Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amici* or their counsel, make a monetary contribution to the preparation or submission of this brief.

[2] See, e.g., Kenneth W. Starr, Patrick E. Higginbotham, Stephanie K. Seymour, William C. Clark, John Criswell & Joe Sneed, THE LAW OF PREEMPTION: A REPORT OF THE APPELLATE JUDGES CONFERENCE (American Bar Association, 1991); Kenneth W. Starr, Preface to FEDERAL PREEMPTION: STATES' POWERS, NATIONAL Interests (Richard A. Epstein & Michael S. Greve eds., 2007); Kenneth W. Starr, *Reflections on Hines v. Davidowitz: The Future of Obstacle Preemption*, 33 PEPP. L. REV. 1 (2005).

2008), and University of California, Irvine School of Law (2008–present). He has also written at length on the subject of preemption.[3]

SUMMARY OF ARGUMENT

At bottom, this is a case about federalism. This Court has long assumed that "the historic police powers of the States [are] not to be superseded by [federal statute] unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). This starting assumption applies with particular force where Congress has legislated in a field that the states have traditionally occupied.

The principle recognized in *Rice* and its many progeny is necessary to protect state sovereignty and to ensure the proper functioning of the political safeguards of federalism. Requiring evidence of a clear and manifest preemptive purpose provides a political check, by affording notice to the states' representatives in Congress, and it also creates a procedural check, by demanding that state-law-displacing choices satisfy the bicameralism and presentment standards of Article I.

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[3] *See, e.g.*, Erwin Chemerinsky, ENHANCING GOVERNMENT 241-45 (Stanford Univ. Press 2008); Erwin Chemerinsky, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES (Aspen Law & Business 3d ed. 2006); Erwin Chemerinsky, *Empowering States: The Need to Limit Federal Preemption*, 33 PEPP. L. REV. 69 (2005); Erwin Chemerinsky, *Empowering States: a Rebuttal to Dr. Greve*, 33 PEPP. L. REV. 91 (2005); Erwin Chemerinsky, *Empowering States When It Matters: A Different Approach to Preemption*, 69 BROOK. L. REV. 1313 (2004).

The *Rice* principle in preemption cases is also consistent with a proper conception of the judicial role. It reduces the probability of erroneous judicial displacement of state law without congressional authorization and prevents preemption analysis from becoming a freewheeling, impressionistic judicial inquiry into congressional intent.

The legal requirements for preemption cannot be satisfied in this case. Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(b)(1) (the "Vaccine Act"), does not provide sufficient evidence of a clear and manifest preemptive purpose to bar design defect claims as a categorical matter. Rather, the language of the statute is just as plausibly (if not more plausibly) construed to allow the continued availability of design defect claims based on a plaintiff's showing of a feasible alternative design for a specific vaccine in a particular case. Even if legislative history could satisfy the *Rice* principle, nothing in the history of the Vaccine Act could possibly meet the requirements for preemption here.

The judgment should be reversed.

ARGUMENT

I. PRINCIPLES OF FEDERALISM REQUIRE EVIDENCE OF A CLEAR AND MANIFEST CONGRESSIONAL PURPOSE TO PREEMPT STATE LAW.

A. The *Rice* Principle Is Well Established.

This Court has long cited the need for a strong indication of congressional intent to overcome the usual assumption that "Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). The Court first articulated its clear statement rule in *Mintz v. Baldwin*, 289 U.S. 346, 350 (1933) ("The intention [to displace state law] must definitely and clearly appear."). It elaborated in *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947), that "the historic police powers of the States [are] not to be superseded by [federal statute] unless that was the clear and manifest purpose of Congress." *Id.* at 230. *See also City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981) (preemption requires "evidence of a clear and manifest purpose"); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146-47 (1963) ("we are not to conclude that Congress legislated the ouster of this California statute . . . in the absence of an unambiguous congressional mandate to that effect").

"In areas of traditional state regulation," the Court "assume[s] that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). A court

has "a duty" to adopt a non-preemptive interpretation despite the presence of a "plausible alternative reading" – even if the "alternative were just as plausible as [the non-preemptive] reading of that text." *Id.*

This Court recently reiterated that it will avoid attributing preemptive force to federal law in cases of statutory ambiguity:

> When addressing questions of express or implied pre-emption, we begin our analysis "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." . . . That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States . . . Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption."

Altria Group, Inc v. Good, 129 S. Ct. 538, 543 (2008) (citations omitted).

The *Rice* principle applies "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied.'" *Wyeth v. Levine*, 129 S. Ct. 1187, 1194 (2009) (citations omitted). It applies to both the "'question whether Congress intended any pre-emption at all' and to 'questions concerning the

scope of intended invalidation of state law.'" *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 260-61 (2004) (citation omitted).

B. The Need For Evidence Of A Clear and Manifest Preemptive Purpose Stems From Important Constitutional Principles.

The *Rice* principle is of constitutional dimension. It arises from the basic axioms of the "system of dual sovereignty between the States and the Federal Government." *Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991). The Framers adopted this "'constitutionally mandated balance of power,'" *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985) (citation omitted), to "reduce the risk of tyranny and abuse from either front," because a "federalist structure of joint sovereigns preserves to the people numerous advantages," such as "a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society" and "increase[d] opportunity for citizen involvement in democratic processes." *Gregory*, 501 U.S. at 458. Furthermore, as the Framers observed, the "compound republic of America" provides "a double security . . . to the rights of the people" because "the power surrendered by the people is first divided between two distinct governments, and then the portion allotted to each subdivided among distinct and separate departments." The Federalist No. 51, p. 266 (M. Beloff ed., 2d ed.1987). *See also* Erwin Chemerinsky, *Empowering States When It Matters*, 69 BROOK. L. REV. at 1332 (federalism "is a means to the end of effective government that minimizes the

possibility of tyrannical rules, provides for the related goal of greater accountability, and sets the stage for vigorous experimentation").

Under this federalist system, the states retain substantial sovereign authority, under both the Tenth Amendment and "[t]he tacit postulates" of the constitutional plan, which then-Justice Rehnquist described as "as much ingrained in the fabric of the document as its express provisions." *Nevada v. Hall*, 440 U.S. 410, 433 (1979) (Rehnquist, J., dissenting). "[T]he States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause." *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990). *See also Alden v. Maine*, 527 U.S. 706, 713 (1999); *Printz v. United States*, 521 U.S. 898, 918-22 (1997); *New York v. United States*, 505 U.S. 144, 155-56 (1992).

The need for evidence of a clear and manifest preemptive purpose derives from the nature of federalism. Preemption analysis must include "due regard for the presuppositions of our embracing federal system, including the principle of diffusion of power not as a matter of doctrinaire localism but as a promoter of democracy." *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 243 (1959).

As this Court explained in *Garcia v. San Antonio Metro. Trans. Auth.*, 469 U.S. 528 (1985), "the States occupy a special and specific position in our constitutional system." *Id.* at 547. Although *Garcia* ended the approach of *National League of Cities v. Usery*, 426 U.S. 833 (1976), which had used principles of federalism as a substantive limit on Congress' commerce power, this Court did not leave

the states bereft of constitutional protection. Instead, this Court substituted procedural checks for the substantive prohibitions of *Usery*. *Garcia* held that state sovereignty is "more properly protected by procedural safeguards inherent in the structure of the federal system than by judicially created limitations on federal power." 469 U.S. at 552.

In order for the "procedural safeguards" of federalism to function, however, Congress must make clear its intent to alter the federal balance and displace state law, particularly in the areas where states have historically exercised their police powers to protect consumers and promote public health, welfare, and safety. "[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance." *United States v. Bass*, 404 U.S. 336, 349 (1971); *see also Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) ("This [*Rice*] assumption provides assurance that 'the federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts.") (citation omitted); Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 COLUM.L.REV. 527, 539-540 (1947).

Requiring evidence of a clear and manifest preemptive purpose provides a political check, by affording notice to the states' representatives in Congress, and it also creates a procedural check, by demanding that state-law-displacing choices satisfy the bicameralism and presentment standards of Article I. *See INS v. Chadha*, 462 U.S. 919, 945-46 (1983) (setting forth the Constitution's Bicameral and Presentment Clauses, Art. I, § 7, cls. 2-3, which "prescribe and define the respective functions of the

Congress and of the Executive in the legislative process"). "The Supremacy Clause thus requires that pre-emptive effect be given only those to federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures." *Wyeth*, 129 S. Ct. at 1207 (Thomas, J., concurring in the judgment).

As this Court recognized in *Gregory v. Ashcroft*, 501 U.S. 452 (1992), according preemptive effect to ambiguous federal statutes would short-circuit the political safeguards of federalism:

> [I]nasmuch as this Court in *Garcia* has left primarily to the political process the protection of the States against intrusive exercises of the Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such exercise. "To give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests."

Id. at 464 (citation omitted). Accordingly, this Court opined that "Congress should make its intention 'clear and manifest' if it intends to pre-empt the historic powers of the States." *Id.* at 461 (quoting *Rice*, 331 U.S. at 230). "'In traditionally sensitive areas, such as legislation affecting the federal balance, the requirement of clear statement assures that the legislature has in fact faced, and intended to

bring into issue, the critical matters involved in the judicial decision.'" *Id.* (quoting *Will v. Michigan Dept. of State Police,* 491 U.S. 58, 65 (1989)). "This plain statement rule is nothing more than an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Id.*

"[B]ecause the States are independent sovereigns in our federal system," this Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic v. Lohr,* 518 U.S. 470, 485 (1996); *see also* Kenneth W. Starr, et al., THE LAW OF PREEMPTION at 40-56 (arguing that a "clear intent" requirement for preemption advances the interests of federalism); Erwin Chemerinsky, *Empowering States*, 33 PEPP. L. REV. at 74-75 ("Even as to express preemption, provisions of federal law that expressly preempt state law should be narrowly construed unless Congress has indicated otherwise.").

The need for evidence of a clear and manifest preemptive purpose is but one of several requirements that protect state sovereignty. Thus, this Court has required that Congress clearly state conditions on grants of federal funds to the States, *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006); that Congress provide a clear statement of intent when it regulates at the outer limit of its Commerce Clause authority, *Jones v. United States*, 529 U.S. 848, 858 (2000); and that it clearly state any intent to subject states to liability under federal statutes. *Will*, 491 U.S. at 65.

Requiring evidence of a clear and manifest preemptive purpose is also consistent with a proper conception of the judicial role. It reduces the probability of erroneous judicial displacement of state law without congressional authorization by ensuring that preemption analysis does not become "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives." *Gade v. National Solid Wastes Management Assn.*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in judgment). *See also Bates*, 544 U.S. at 459 (preemption is not "a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict." (Thomas, J., concurring in judgment in part and dissenting in part) (internal quotation marks and citation omitted).

C. The Supremacy Clause Supports The Need For Evidence Of A Clear And Manifest Preemptive Purpose.

Although the Supremacy Clause of Art. VI, cl. 2, means that federal law prevails in the event of any clash between the two concurrent sovereigns of Our Federalism, the Supremacy Clause supports the *Rice* principle in two respects. First, in adopting the Supremacy Clause, the Framers deliberately chose not to vest Congress with untrammeled authority over state law. The Clause was chiefly the product of proposals crafted by James Madison, introduced early in the proceedings at the Constitutional Convention.[4]

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[4] *See* Kenneth W. Starr, et al., THE LAW OF PREEMPTION at 5.

Initially, Madison introduced an even stronger clause that would have granted Congress the power "to negative all laws which to [national legislators] shall appear improper."[5] Proponents of the Small State, or New Jersey Plan, rejected this stronger proposed clause due to their mistrust of such a strong federal government.[6] In particular, George Mason warned: "[T]he Danger is that the national [legislature] will swallow up the State Legislatures."[7] Hence, in their consideration of the Supremacy Clause, the Framers elected to retain important limits on the power of the national government.

The Supremacy Clause also supports the *Rice* principle in another respect. Precisely because the Clause represents strong medicine, courts must inquire to satisfy themselves that Congress has actually decided to invoke it. As the Court has observed, the Supremacy Clause gives the Federal Government "a decided advantage in [a] delicate balance" between federal and state authority. *Gregory*, 501 U.S. at 460. "As long as it is acting within the powers granted it under the Constitution, Congress may impose its will on the States" – a prerogative that this Court has described as an "extraordinary power in a federalist system." *Id.* Requiring evidence of a clear and manifest preemptive purpose ensures that courts recognize

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[5] *Id.* at 7 (quoting 1 The Records of the Federal Convention of 1787, at 162 (records of June 8, 1787) (M. Farrand rev. ed., 1966)).

[6] *Id.* at 7-8.

[7] *Id.* at 6 (quoting 1 The Records of the Federal Convention of 1787, at 160 (records of June 7, 1787)).

this "extraordinary power" only when it is proper to do so.

In sum, the *Rice* principle is an important element in the constellation of constitutional doctrines that protect state sovereignty.

II. THE LEGAL REQUIREMENTS OF PREEMPTION CANNOT BE SATISFIED IN THIS CASE.

Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(b)(1) (the "Vaccine Act") provides:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.[8]

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[8] 42 U.S.C. § 300aa-22(b) provides in full:

> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

This statutory provision does not meet the legal requirements for preemption of all vaccine design defect claims, whether the vaccine's side effects were unavoidable or not. We reach this conclusion for several reasons.

First, on its face, Section 22(b)(1) does not evidence a clear and manifest purpose to preempt all design defect claims as a categorical matter. An equally plausible (if not more plausible) interpretation is that the inquiry of whether vaccine side effects "were unavoidable" must be made on a case-by-case basis rather than categorically. If a particular plaintiff could show that her injury at issue was avoidable, for example, through the use of a feasible alternative design for a specific vaccine, then she would satisfy the language of the statute, because

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(2) For purposes of paragraph (1), a vaccine shall be presumed to be ac-companied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in sub-paragraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

she would have demonstrated that the side effects were *not* unavoidable.

If Congress had intended to bar all design defect claims with respect to vaccines, and to allow only manufacturing defect and failure-to-warn claims, it could have written a much simpler statute. As one commentator has observed:

> [The drafters] had a very simple option at their disposal: they could have omitted the words "that were unavoidable" from the provision. The result would have been a statute that shielded vaccine manufacturers from liability in civil actions where "the injury or death resulted from side effects even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[9]

Such alternative language would have preserved manufacturing defect and failure-to-warn liability while precluding claims for defective design where the vaccine was properly prepared. The fact that Congress did not adopt such a straightforward approach indicates that it did not intend to bar all design defect claims categorically.

In *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), this Court used a similar analysis of possible alternative language to support a holding of non-preemption. *See id.* at 448-49 (rejecting an

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[9] Nitin Shah, "Note: When Injury Is Unavoidable: The Vaccine Act's Limited Preemption Of Design Defect Claims," 96 VA. L. REV. 199, 217 (2010).

interpretation that would "read[] . . . words out of the statute.... This amputated version . . . would no doubt have clearly and succinctly commanded the pre-emption of *all* state" tort claims for defective design) (emphasis in original).

Construing the Vaccine Act to bar all design defect claims would introduce the same vice. It would require ignoring part of Section 22(b)(1) – in particular, the clause "that were unavoidable." If the meaning of Section 22(b)(1) were unaffected by the presence or absence of the clause, then that clause would be rendered superfluous, in violation of the "settled rule that a statute must, if possible, be construed in such fashion that every word has some operative effect." *United States v. Nordic Village, Inc.*, 503 U.S. 30, 36 (1992).

Next, the structure of the Vaccine Act militates in favor of an interpretation of Section 22(b)(1) that does not preempt design defect claims categorically. Although the Vaccine Act creates a mandatory national compensation program, the Act contains a savings clause that expressly contemplates the preservation of state law tort claims.[10] It affords claimants three separate chances to exit the administrative compensation program and file suit under state law, including the explicit opportunity to elect "to file a civil action for damages" after receiving

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[10] Section 22(a) provides: "Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a).

a judgment from the Vaccine Court.[11] Section 22(b) preserves at least some (and arguably all) manufacturing defect claims, as well as many failure-to-warn claims. Section 23(d)(2) envisions the award of punitive damages against vaccine manufacturers and immunizes them from such damages on a showing of compliance with all material requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, absent fraud or other criminal misconduct.[12] In short, the structure of the Vaccine Act shows that it is not a statute aimed at categorically ousting state tort law from vaccine-related litigation; to the contrary, the Act clearly envisions the continued availability of state-law claims.

In fact, the only portion of Section 22 that carries the title "Preemption" – Section 22(e) – does not bar state-law tort claims at all. To the contrary: Section 22(e) bars states from establishing new laws that would interfere with claimants' right to sue under state law.[13] Thus, the "preemption" portion of Section 22 facilitates the continued prosecution of claims in state court, rather than restricting them.

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[11] A claimant may reject or appeal the judgment of the Vaccine Court. 42 U.S.C. § 300aa-21(a). Prior to that opportunity, a claimant may opt out 240 days after filing a petition if the special master assigned to the case has not yet reached a decision, or 420 days after filing the petition if the court has failed to enter a judgment. *Id.* § 300aa-21(b).

[12] 42 U.S.C. § 300aa-23(d).

[13] Section 22(e) provides: "No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part."

Even if legislative history could provide evidence of a clear and manifest preemptive purpose, nothing in the history of the Vaccine Act could possibly meet the requirement here. The purpose and summary section of the House Report on the Vaccine Act states that "[v]accine-injured persons . . . [who] reject a judgment and award made under the compensation program . . . may file a civil action for damages relating to a vaccine injury just as he or she may have done prior to the enactment of the legislation."[14] Such language reassured states that Congress was *not* displacing design defect claims as a categorical matter.

The legislative history further indicates that, in discussing Section 22(b), the House Report referred to the principle of Comment k of Section 402A of the Second Restatement of Torts.[15] Comment k exempts from strict liability certain

> [u]navoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their

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[14] H.R.Rep. No. 908, 99th Cong., 2d Sess. 4, *reprinted in* 1986 U.S. Code Cong. & Admin. News 6287, 6344-45.

[15] *See* H.R. Rep. No. 99-908, pt. 1, at 25 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6366 ("This provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second)"); *see* also H.R. Rep. No. 99-908, pt. 1, at 26, *reprinted in* 1986 U.S.C.C.A.N. at 6367 ("The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding 'unavoidably unsafe' products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.").

> intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many . . . drugs, vaccines, and the like. . . .

Restatement (Second) of Torts § 402A cmt. k (1965). Under the majority approach to comment k, a court must make a case-by-case determination of whether a certain side effect is unavoidable. Comment k does not entail a categorical pronouncement that a particular product is unavoidably unsafe in all circumstances. "The longstanding majority approach is to analyze Comment k's applicability on a case-by-case basis."[16]

Because there is insufficient evidence of a clear and manifest preemptive purpose, Section 22(b)(1) cannot be interpreted as preempting design defect claims on a categorical basis. Properly construed, Section 22(b)(1) does not preempt all design defect claims against vaccine manufacturers on a categorical basis, but rather provides that such a manufacturer cannot be held liable for defective design only if it is determined, on a case-by-case

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[16] Nitin Shah, Note, 96 VA. L. REV. at 235; *see also* Joanne Rhoton Galbreath, Annotation, Products Liability: What is an "Unavoidably Unsafe" Product, 70 A.L.R. 4th 16, 41–47 (1989); Am. L. Prods. Liab. 3d § 17:47 (1987) ("Most courts have stated that there is no justification for giving all prescription drug manufacturers blanket immunity from strict liability under Comment k, and that whether a particular drug is unavoidably unsafe should be determined on a case-by-case basis.").

basis, that the particular vaccine was unavoidably unsafe.

CONCLUSION

The judgment below should be reserved.

Respectfully submitted,

JONATHAN S. MASSEY
Counsel of Record
MASSEY & GAIL, LLP
1325 G St. NW
Suite 500
Washington, D.C. 20005
(202) 652-4511

MICHAEL R. HUGO
277 Dartmouth St.
Boston, MA 02116
(617) 448-4888

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AMICUS CURIAE BRIEF

Supreme Court, U.S.
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THE CLERK

No. 09-152

IN THE
Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ,
PARENTS AND NATURAL GUARDIANS OF
HANNAH BRUESEWITZ, A MINOR CHILD,
AND IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES,
WYETH-AYERST LABORATORIES, WYETH LEDERLE,
WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,
Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Third Circuit

BRIEF OF VACCINE INJURED PETITIONERS BAR ASSOCIATION, THE GEORGE WASHINGTON UNIVERSITY LAW SCHOOL VACCINE INJURY CLINIC, AND ZENORIA PHILLIPS DELOATCH, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF MOSHELLA F. ROBERTS, AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

JENNIFER ANNE GORE MAGLIO
Counsel of Record
MAGLIO CHRISTOPHER TOALE
& PITTS LAW FIRM
1751 Mound Street
Second Floor
Sarasota, Florida 34236
(941) 952-5242
(jmaglio@mctplaw.com)

PROFESSOR PETER H. MEYERS
DIRECTOR, VACCINE INJURY CLINIC
THE GEORGE WASHINGTON
UNIVERSITY LAW SCHOOL
2000 G Street, N.W.
Washington, D.C. 20052
(202) 994-7463

June 1, 2010

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INTEREST OF *AMICI CURIAE*[1]

Amicus curiae, the Vaccine Injured Petitioners Bar Association (hereinafter "Petitioners Bar") is a voluntary bar association comprised of attorneys who represent petitioners in the National Vaccine Injury Compensation Program (hereinafter "Vaccine Program" or "Program"). Members of the Petitioners Bar have assisted the families of children and adults who have suffered adverse effects from vaccinations since the inception of the Vaccine Program. The organization and its members have a professional responsibility to ensure that the families of the vaccine-injured receive justice as Congress intended – swiftly, with generosity and certainty. To that end, members of the Petitioners Bar have testified before Congress numerous times concerning vaccine injuries and the Vaccine Program. It is in the performance of their professional duties that these *amici* feel compelled to describe to this Court the injustice worked upon a small group of petitioners by the lower court's decision – an injustice never intended by Congress.

Amicus curiae, The George Washington University Law School Vaccine Injury Clinic was established in 1994 at the suggestion of several judges of the U.S. Court of Federal Claims who saw a need for additional knowledgeable counsel in vaccine injury cases.

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represents that it authored this brief and that no person or entity other than *amici* or their counsel made a monetary contribution to the preparation or submission of the brief. Counsel for *amici* represents that counsel for all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amicus* briefs have been filed with the Clerk.

The Vaccine Injury Clinic represents the families of young children in vaccine compensation proceedings through its law student-attorneys. Through the efforts of its students and faculty, the Vaccine Injury Clinic has obtained compensation for children with severe mental and physical disabilities and has prevailed in appeals to the U.S. Court of Appeals for the Federal Circuit on significant vaccine matters.

Amicus curiae, Mrs. Phillips DeLoatch is a mother who lost her healthy child four days after receipt of the Gardasil vaccine. Mrs. DeLoatch is a petitioner in the Vaccine Program seeking justice for the loss of her daughter. Mrs. DeLoatch's case exemplifies a vaccine claim that may not be adequately resolved within the Vaccine Program, thereby requiring resort to the tort system. Should Mrs. DeLoatch opt out of the Vaccine Program, and allege in a traditional tort suit that her daughter's death could have been avoided with an alternative design, she would be precluded from pursing her claim by the Third Circuit's opinion below. As a result of the Third Circuit's interpretation of the National Childhood Vaccine Injury Act of 1986 (hereinafter "Vaccine Act" or "Act"), families of vaccine-injured children, like Mrs. DeLoatch, could find themselves without remedies in either the vaccine court or the tort system.

These *amici* would respectfully submit that the members of Congress did not intend for children to fall through the cracks in the system they created. As Senator Robert T. Stafford explained, "Our obligation is not to the drug companies nor the doctors. Indeed, our highest obligation is not even to the parents who may have suffered grievously; our highest obligation is to the children." *Hearing on S. 827 Before the S. Comm. on Labor & Human Res.*, pt. 1,

99th Cong. 16 (1985). Senator Paula Hawkins echoed this sentiment in her written statement to the House Subcommittee on Health and the Environment, "But I think it is equally important that in our desire to assure a continuous supply of childhood vaccines, that we are not stampeded into modif[y]ing the bill to the detriment of the injured children. They are and must remain our first priority." *Hearings on H.R. 5810 Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Commerce*, 98th Cong. 354 (1985).

Amici submit this brief in hopes that their experience and perspectives will assist the Court in understanding the practical implications of the decision on review.

SUMMARY OF ARGUMENT

Congress created the National Vaccine Injury Compensation Program to ensure that all children injured by vaccines would receive compensation quickly, easily, and with certainty and generosity. To meet these goals, the Vaccine Program limits the scope and timing of compensation proceedings. Evidence is limited. Motion practice is limited. There is no discovery as a matter of right.

In theory, such limits streamline the compensation process to the benefit of families enduring the financial and emotional costs of vaccine injuries. However, not all claims can be fully and fairly adjudicated within the Vaccine Program. For example, for the families of those injured by vaccines that have not been widely studied, the publicly available information necessary to support a claim in the Vaccine Program does not exist.

Mrs. Phillips DeLoatch's experience in the Vaccine Program illustrates how the limits put in place by

Congress to provide swift justice to the vaccine-injured can become barriers to justice. Mrs. DeLoatch represents her daughter's estate as a petitioner in the Vaccine Program. Mrs. DeLoatch lost her daughter after she received the cervical cancer vaccine, Gardasil. There are currently five other families in the Vaccine Program who have similarly lost their daughters after a Gardasil vaccination.

To prove how the Gardasil vaccine caused her daughter's death, Mrs. DeLoatch needs specific studies and information on the vaccine, which information is currently held only by Gardasil's manufacturer, Merck & Company, Inc. In traditional tort claims, the litigation tool of discovery could be used to obtain this information. Because of the restraints on discovery built into the Vaccine Program, such a tool is not available to Mrs. DeLoatch and she has been denied discovery from the vaccine manufacturer. Acknowledging the damaging effect of her inability to obtain discovery on her claim, the Special Master in Mrs. DeLoatch's case has informed her that she may leave the Vaccine Program and file suit against the vaccine manufacturer to pursue her claim.

Without the information she must obtain from the manufacturer, Mrs. DeLoatch cannot proceed in the Vaccine Program. To obtain this information, Mrs. DeLoatch must leave the Program and file a traditional tort suit against the manufacturer showing that her daughter's death could have been avoided through a safer design. The manufacturer will undoubtedly defend this design defect suit by arguing that Mrs. DeLoatch may pursue her claim only in the forum of the Vaccine Program. Pursuant to the Third Circuit's ruling, Mrs. DeLoatch and petitioners

like her have nowhere to go to seek justice. Such a result is the antithesis of Congress's intent in creating the Vaccine Program.

ARGUMENT

I. CONGRESS CREATED THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM TO PROVIDE SIMPLE AND SPEEDY JUSTICE FOR THE FAMILIES OF VACCINE-INJURED CHILDREN.

Congress established the National Vaccine Injury Compensation Program in 1986 as a means to provide swift justice to the families of children and adults injured by vaccines. *See* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, tit. III, 100 Stat. 3743, 3755 (codified as amended at 42 U.S.C. § 300aa *et seq.*). From its inception, the purpose of the Vaccine Program was to "establish a simple, no-fault, low transaction cost, nonadversarial, and effective national program for assuring the provision of just compensation to children and others who have sustained vaccine-related injury." H.R. 5810, 98th Cong. § 2(b)(1) (1984); *Hearings on H.R. 5810*, *supra*, at 5.

A. Prior to the creation of the Vaccine Program, families, already emotionally and financially stressed by their children's injuries, had to seek relief in the traditional tort system with its delays and inconsistent results.

In creating the Vaccine Program, Congress recognized that some individuals inevitably suffer adverse reactions to vaccines. *See* H.R. 5810, *supra*, § 2(a)(2); *Hearings on H.R. 5810*, *supra*, at 57, 117 (statements of Rep. Henry A. Waxman). Families can be devastated by such vaccine injuries. An adverse vaccine

reaction can cause a range of disabilities, paralysis and even death. *See* H.R. Rep. No. 106-977, at 2 (2000). To provide for their injured child or parent, a family may face enormous expenses, including residential care, therapy, medical equipment, and drugs. *Id.* Before the creation of the Vaccine Program, families had to turn to traditional tort litigation in an attempt to seek compensation for these overwhelming medical expenses. *Id.*

In the 1980s, Congress became concerned that families were subject to years of emotional and financial stress in their efforts to seek relief through the traditional tort system. *See, e.g., Hearing on H.R. 1780, H.R. 4777, and H.R. 5184 Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Commerce*, 99th Cong. 1-2 (1987) (statement of Rep. Henry A. Waxman); H.R. Rep. No. 99-908, pt. 1, at 6 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6347. Testifying before the House Subcommittee on Health and the Environment, Dr. Martin Smith, President-Elect of the American Academy of Pediatrics explained, "Yet, when a small percentage of serious injuries inevitably occurs, we abandon those children to the slow, tedious, uncertain tort process for appropriate compensation." *Hearings on H.R. 5810, supra*, at 5. Describing the stresses placed upon parents, Dr. Smith stated, "Under the present system, parents are forced to revisit over an extended period of time the tragedy that has occurred with their children and relive a difficult emotional crisis. The needs of these children are immediate. They cannot wait 6 to 8 years for a possible settlement." *Id.*

After years of hearing from countless experts like Dr. Smith, as well as the parents of injured children, members of Congress agreed on the need for a simple

and speedy compensation program for vaccine-injured children. Senator Paula Hawkins, speaking on behalf of the Senate Committee on Labor and Human Resources, stated, "I believe we all agree on the need to modify the current method of compensating children for injuries. I think these children have an urgent need and deserve simple justice quickly." *Hearing on S. 2117 Before the S. Comm. on Labor & Human Res.*, 98th Cong. 290-91 (1984). At a hearing conducted by the same committee in 1985, Senator Hawkins challenged her colleagues to move forward with a compensation program, saying, "it is time we ... provide just and expedited compensation for those few children who are injured by an adverse reaction." *Hearing on S. 827*, pt. 1, *supra*, at 6.

B. Congress designed the Vaccine Program with restrictions to the timing of proceedings and the scope of evidence to be considered for the purpose of ensuring a swift and generous resolution of vaccine claims.

In crafting the Vaccine Program, Congress sought to provide the swift justice called for by its members and the parents and doctors who participated in its hearings. In its report on the Vaccine Act, the House Committee on Energy and Commerce set forth the Act's purpose: "to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, pt. 1, *supra*, at 3, *reprinted in* 1986 U.S.C.C.A.N. 6344. As this Court noted in *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995), "For injuries and deaths traceable to vaccinations, the Act establishes a scheme of

recovery designed to work faster and with greater ease than the civil tort system."

The Vaccine Act initially required that a judgment be rendered "as expeditiously as practicable but not later than 365 days after the date on which the petition was filed." Vaccine Act § 2112(d)(3), 100 Stat. 3762. To assist the courts in meeting this one year deadline, the Act included a vaccine injury table that created a presumption of vaccine-related injury in certain circumstances. *Id.* § 2114(a), 100 Stat. 3764. The Act also provided for special masters to assist the court in quickly addressing the petitioner's compensation claim. *Id.* § 2112(c), 100 Stat. 3761. *See also Shalala v. Whitecotton*, 514 U.S. at 270 ("Special masters in the Court of Federal Claims hear vaccine-related complaints which they adjudicate informally, within strict time limits, subject to similarly expeditious review." (citations omitted)). While the Act authorized special masters to require information and testimony as may be reasonable and necessary to determine entitlement to compensation, it limited discovery as a matter of right. *See* Vaccine Act § 2112(c)(2), 100 Stat. 3761-62; R.U.S.C.F.C., App. B, Vaccine Rule 7 ("There shall be no discovery as a matter of right.").

Thus, Congress designed the Vaccine Program with compassion for the families who would participate in the Program. As Senator Orrin G. Hatch stated in his Opening Statement to the Committee on Labor and Human Relations, "It is compassion which drives this legislative process; it is concern for children and their health." *Hearing on S. 827*, pt. 1, *supra*, at 1. The Program was designed to provide simple and speedy relief for families enduring the financial and emotional struggles attendant to serious injuries –

injuries their children had received as a result of mandatory vaccinations. It was designed to provide swift justice for those families.[2]

II. NOT EVERY CASE CAN BE FULLY AND FAIRLY LITIGATED WITHIN THE CONFINES OF THE VACCINE PROGRAM.

The Vaccine Program can deliver the swift justice Congress intended. It can provide a relatively quick resolution for the families of those injured by vaccines. In some cases, however, the Program, as designed, cannot provide swift justice. Mrs. Phillips DeLoatch is the petitioner in one such case. Her experience provides a stark illustration of how the Program cannot fully resolve all vaccine claims.

A. Mrs. Phillips DeLoatch suffered the loss of her daughter after receipt of the Gardasil vaccine and now has learned that her case is one where the Vaccine Program cannot deliver swift justice.

Mrs. DeLoatch is the personal representative of her daughter's estate. *See DeLoatch v. Sec'y of Health & Human Servs.*, No. 09-171V, slip op. at 1 (Fed. Cl. Apr. 27, 2010). Moshella F. Roberts, Mrs. DeLoatch's daughter, passed away in April 2008, shortly after receiving the Gardasil vaccine. *Id.* at 2. Moshella was 20, a young woman who worked in home health care. *Id.* Four days after receiving the Gardasil vaccine, Moshella was found dead. *Id.* Moshella had no previous health problems.

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[2] In its Report on the Act, the House Committee on Energy and Commerce noted, "without such quick and certain conclusion of the proceedings, the compensation system would work an injustice upon the petitioner." H.R. Rep. No. 99-908, pt. 1, *supra*, at 17, *reprinted in* 1986 U.S.C.C.A.N. 6358.

After performing an autopsy the day after her death, the medical examiner ruled Moshella's cause of death to be undetermined. *Id.* Convinced that the administration of the Gardasil vaccine played a role in her otherwise healthy daughter's death, Mrs. DeLoatch filed a petition in the Vaccine Program. *Id.*

B. Typically, a vaccine proceeding moves relatively quickly through the process of gathering medical records and medical expert opinions to the causation hearing.

Typically, a petition for compensation in the Vaccine Program is supported by the injured party's medical records and medical expert affidavits. *See* Office of the Special Masters, U.S. Court of Federal Claims, Guidelines for Practice Under the National Vaccine Injury Compensation Program at 5-7 (2004) (hereinafter "Special Masters Guidelines"), *available at* http://www.uscfc.uscourts.gov/sites/default/files/OSMGuidelines1104.pdf. The respondent in the proceeding, the Secretary of Health and Human Services, as represented by the attorneys of the Department of Justice, has the opportunity to review the medical records and obtain its own medical expert opinions regarding whether the injury claimed is vaccine related. *Id.* at 8-9. *See also* 42 U.S.C. § 300aa-12(b)(1). At such point, the respondent may choose to concede that the injury is vaccine related and the parties move on to the question of the amount of compensation to be paid. *See* Special Masters Guidelines at 8-10.

If the respondent refuses to concede that the injury claimed was caused by or related to the receipt of a vaccine, then the special master presiding over the petition conducts a causation hearing to determine

that issue.[3] *Id.* at 12-14. At the causation hearing, the special master considers the medical records, the testimony of the petitioner's family and the opinions of the medical experts. *Id.* For the most part, there is no discovery or motion practice by the parties. *Id.* at 11-12. The parties proceed to hearing with the medical records, limited testimony and expert opinions. *Id.* at 12-14. There is no right to interrogatories or depositions. *See* H.R. Rep. No. 99-908, pt. 1, *supra*, at 17, *reprinted in* 1986 U.S.C.C.A.N. 6358. This is how Congress's swift justice is achieved.

As would be expected under such a system, the opinions of medical experts become paramount to the outcome of a petitioner's claim. Experts, in turn, rely heavily on both their own medical experience and the body of medical literature that may explain the relationship between a particular vaccine and adverse reactions that have been associated with that vaccine over time.

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[3] This discussion presumes that the case does not involve an injury listed on the vaccine injury table and is thus an "off table" case. Off-table cases comprise the majority of cases filed in recent years. *See* U.S. Dep't of Health & Human Servs., National Vaccine Injury Compensation Program Strategic Plan 1, 5 (2006). At this point in time, every Gardasil case must be an off-table case, as no compensable injuries have been added to the vaccine injury table since Gardasil became covered by the Vaccine Act. *See* Health Res. & Servs. Admin., U.S. Dep't of Health & Human Servs., *National Vaccine Injury Compensation Program – Vaccine Injury Table* (effective date Nov. 10, 2008), *available at* http://www.hrsa.gov/vaccinecompensation/table.htm#a; 42 C.F.R. § 100.3 (2009); Vaccine Injury Compensation, 73 Fed. Reg. 59,530 (Oct. 9, 2008) (amending 42 C.F.R. § 100.3 to remove an item from the vaccine injury table).

C. Medical experts cannot formulate well-founded opinions where vaccines, such as Gardasil, have not been well studied, resulting in a petitioner's inability to prove his case.

When a vaccine has been studied and administered for a number of years such that possible adverse reactions have been identified, the relevant medical literature is available and accessible by the medical experts. However, with the introduction of numerous new vaccines in recent years and ongoing, incomplete studies of the safety of such vaccines, there are times when the medical literature is not sufficiently developed for use by a medical expert in formulating an opinion.

Vaccine injuries are almost always difficult to detect and sometimes difficult to define. In most cases, there are no objective medical tests available to clearly demonstrate the role the vaccine has played in causing injury. *See, e.g., Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) ("The DPT vaccine leaves no 'footprint' evidencing that it was the catalyst for a particular injury."). Often, vaccine injuries manifest themselves in complex neurological or immunological disorders. *See, e.g.*, Michael E. Horwin, Comment, *Ensuring Safe, Effective and Necessary Vaccines for Children*, 37 Cal. W. L. Rev. 321, 329-30 (2001). Due to the fact that adverse vaccine reactions affect a statistically small group of people, it is usually impossible for the medical community to track trends that allow them to identify adverse reactions with anything approaching scientific certainty. Physicians and scientists are hampered in these efforts by the weaknesses of the Vaccine Adverse Events Reporting System

("VAERS"), which, as a passive, voluntary reporting system, may lack complete or relevant information. *See* H.R. Rep. No. 106-977, *supra*, at 9.

For these reasons, the system of swift justice embodied by the Vaccine Program can grind to a halt when faced with a dearth of medical literature relating to a vaccine or injury. Lacking relevant literature, the parties' experts cannot develop or test theories of causation. The experts may have no supportive medical literature to corroborate their testimony. Lacking their experts' opinions, the parties and the special masters cannot proceed to the causation hearing.

This is exactly the situation in which Mrs. DeLoatch finds herself. Gardasil has been widely touted as the first vaccine developed to prevent cervical cancer. *See* News Release, U.S. Food & Drug Admin., FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus (June 8, 2006), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108666.htm. It was approved by the Food and Drug Administration ("FDA") on June 8, 2006, in a fast-track review process. *Id.* *See also* Judicial Watch, Inc., *A Judicial Watch Special Report: Examining the FDA's HPV Vaccine Records* 3-4 (2008) (hereinafter "Judicial Watch Special Report"), *available at* http://www.judicialwatch.org/documents/2008/JWReportFDAhpvVaccineRecords.pdf. The vaccine had been on the market less than two years when Moshella Roberts received her shot. Little medical literature addressed adverse reactions to the Gardasil vaccine at the time of Moshella's death. Little more has been published since her death. And so Mrs. DeLoatch and her med-

ical experts find themselves at the forefront of a new area of research and study – not a desirable place to be when studies take years and one is seeking swift justice.

Gardasil is the trade name for the Quadrivalent Human Papillomavirus Recombinant Vaccine, which was created and is marketed by Merck & Company, Inc. (hereinafter "Merck"). *See* Barbara A. Slade et al., *Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine*, 302 J. Am. Med. Ass'n 750, 750 (2009). It is licensed for use in girls between the ages of 9 and 26 and is administered in a series of three shots. *Id.*

Gardasil is designed to prevent young women from being infected by four specific strains of Genital Human Papillomavirus ("HPV"). *See* Judicial Watch Special Report at 3. There are more than 30 strains of HPV. *Id.* In most cases of HPV, the body's immune system will fight off the virus. *Id.* However, if the body's immune system is not able to fight off the virus, some strains of HPV will cause genital warts and other strains will develop into cervical cancer. *Id.* Gardasil guards against two strains of HPV that can cause genital warts and two strains that may lead to cervical cancer. *Id.* It is unknown how long Gardasil provides such protection before a booster shot is required, although Merck has estimated at least 2.5 to 3.5 years. *Id.* at 12.

As part of its approval of Gardasil, the FDA required that Merck conduct a safety surveillance study that would include 44,000 vaccinated subjects who would be followed for 60 days for general short-term safety. *Id.* at 13. *See also* Letter from Norman W. Baylor , Ph. D., Director, Office of Vaccines, U.S. Dep't of Health & Human Servs., to Dr. Patrick Brill-

Edwards, Director, Worldwide Regulatory Affairs, Merck & Company, Inc. (June 8, 2006), *available at* http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm111283.htm. Merck was also required to follow these young women for six months following their vaccinations to monitor for new autoimmune disorders, rheumatic conditions, or thyroiditis. *Id.* The study was to be completed by June 30, 2009, and submitted to the FDA by September 30, 2009. *Id.* Although past due at this point, this safety surveillance study has not been released and is listed by the FDA's website as delayed. *See* U.S. Food & Drug Admin., Postmarket Requirements and Commitments, *available at* http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm (updated quarterly, last updated Apr. 30, 2010) (hereinafter "FDA Postmarket Requirements").

While Merck has not completed its study of the Gardasil vaccine, there have been two publications that have reviewed adverse reactions to Gardasil as reported in the VAERS database. In June 2008, Judicial Watch issued its Special Report on Gardasil in which it cited 38 reports of Guillain-Barre Syndrome, 78 reports of genital warts, and 18 reports of deaths following receipt of the Gardasil vaccine as reported in the VAERS database. *See* Judicial Watch Special Report at 4, 14-15. In June 2009, Judicial Watch updated its review and reported a new total of 47 deaths associated with Gardasil as reported in the FDA's VAERS database. *See* Judicial Watch, Inc., *Vaccine Adverse Effects Report System (VAERS) Cumulative Deaths Report* 1 (2009), *available at* http://www.judicialwatch.org/files/documents/2009/vaersdeathsALL_20090616.pdf. Of those 47 deaths

reported, at least 27 listed the cause of death as being unknown. *Id.*

In August 2009, doctors from the Centers for Disease Control ("CDC") and the FDA published their review of VAERS reports involving the Gardasil vaccine in the Journal of the American Medical Association (hereinafter "JAMA"). *See* Slade et al., *supra.* The JAMA article concluded that the rate of adverse effects following immunization with Gardasil were not greater than the background rates compared with other vaccines. *Id.* at 750. The study suggested, however, that there were disproportional reports of some reactions. *Id.* The authors additionally noted the limitations of a review of reports in the VAERS system due to the potential for underreporting. *Id.* at 756. Moreover, a majority of the reports came from the vaccine manufacturer, which the authors found did not include sufficient information to allow medical review. *Id.*

Thus, the primary published studies regarding adverse reactions to the Gardasil vaccine have simply been surveys of incidents reported in the VAERS database – a database that the study authors and others have noted is limited by potential underreporting and by incomplete reporting. *Id.* at 750. Notably, many of the VAERS reports that are incomplete were entered into VAERS by Merck. *Id.* at 756. In addition, Merck has failed to timely submit the large-scale study of Gardasil safety ordered by the FDA. *See* FDA Postmarket Requirements, *supra.*

D. Lacking medical literature and completed safety studies, Mrs. DeLoatch's vaccine proceeding has stalled.

What all this means for Mrs. DeLoatch is that there is virtually no medical literature on which to

rely in explaining the death of her daughter. Until additional studies are reported, Mrs. DeLoatch and her medical experts are stuck with little evidence but a strong suspicion that a healthy young woman died as a result of receiving the Gardasil vaccine – a suspicion that is bolstered by the proximity in time between Moshella's receipt of the vaccine and her death and the fact that no other causes of death or health problems were found by the medical examiner. Such suspicion is insufficient to support a finding of causation in either a vaccine compensation proceeding or a traditional tort action.

As of May 2010, the families of six young women, including Mrs. DeLoatch, have filed petitions for compensation in the Vaccine Program following the deaths of their daughters after receipt of the Gardasil vaccine. *See* Health Res. & Servs. Admin., U.S. Dep't of Health & Human Servs., *National Vaccine Injury Compensation Program – Statistics Reports: Claims Filed and Compensated or Dismissed by Vaccine* (May 5, 2010), *available at* http://www.hrsa.gov/vaccinecompensation/statistics_report.htm#claims_filed. An additional 48 petitions have been filed in the Vaccine Program for injuries associated with the Gardasil vaccine. *Id.* Many of these families will find themselves in the same awkward position as Mrs. DeLoatch. They will be hindered by the lack of medical evidence and literature. For these families, swift justice will become slow justice or no justice.

For Mrs. DeLoatch, the search for answers continues. Mrs. DeLoatch's counsel sent the medical records and the medical examiner's report to a respected pathologist for review. *See DeLoatch v. Sec'y of Health & Human Servs.*, slip op. at 2. On

initial review, Moshella's body revealed nothing of the cause of her death. The expert pathologist needed to look further and the question became – where? With no medical literature discussing the mechanisms by which Gardasil could cause an adverse vaccine reaction, where could the pathologist begin to look? Even the safety studies required by the FDA, which may have indicated the types of reactions found, have not been completed.

III. TO OBTAIN THE DISCOVERY HER PETITION REQUIRES, MRS. DELOATCH HAS NO OPTION BUT TO SEEK TORT RELIEF OUTSIDE THE VACCINE PROGRAM, AN OPTION THE THIRD CIRCUIT HAS HELD CONGRESS INTENDED TO DENY HER.

The only actor in possession of additional information that could provide Mrs. DeLoatch with the answers to the question of her daughter's death is Merck, the vaccine manufacturer. Merck is conducting the ongoing and overdue safety study of 44,000 young women vaccinated with Gardasil, as required by the FDA. *See* FDA Postmarket Requirements, *supra*. Merck is also the party in possession of the facts behind the majority of adverse reactions reported to the VAERS database. *See* Slade et al., *supra*, at 756. Reports that doctors from the CDC and the FDA found lacked sufficient information with which to conduct a medical review. *Id.* At this point, most of the data regarding adverse effects of the Gardasil vaccine is held by its manufacturer, which is, understandably, not keen on releasing such data.

A. Discovery is an important litigation tool that, on many occasions, has revealed problems with drugs that the drug manufacturers withheld from the public.

Traditionally, tort litigation has provided litigants and the public with important insights to a product's safety. "Today we have a much better understanding of the risks of asbestos, tobacco, ultra-absorbent tampons, and the Dalkon Shield, thanks to tort litigation brought against these companies." Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 Geo. L.J. 693, 711 (2007). Calling it the education effect of tort law, one commentator explained that pretrial discovery has frequently unearthed industry practices with respect to products like breast implants, Vioxx,[4] and antidepressants that "might otherwise never have seen the light of day." Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DePaul L. Rev. 293, 302 (2007).

In these cases, manufacturers resisted disclosing their internal documents that, through discovery, were uncovered and publicly exposed. *See* Wagner, *supra*, at 711. For example, in "the litigation brought against the manufacturers of Vioxx and Prozac, documents produced during discovery revealed additional information about the manufacturer's internal knowledge about product harms and led to increased public demand for more vigorous oversight of drug manufacturers." *Id.* at 712.[5]

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[4] Vioxx was developed by Merck. *See Merck & Co. v. Reynolds*, No. 08-905, 2010 WL 1655827, at *5 (U.S. Apr. 27, 2010).

[5] In an April 2008 article reported in the distinguished publication, the Journal of the American Medical Association, the

In drafting the Vaccine Act, Congress was aware of the benefit of discovery in tort litigation. At hearings on the Act, attorneys for vaccine-injured children testified as to how they had reviewed the records of the vaccine manufacturers through discovery in litigation. *See Hearings on H.R. 5810, supra*, at 217 (testimony of Boyd McDowell III).

Cognizant that litigation and discovery create incentives for greater vaccine safety, Congress created a compensation program that did not permit discovery as a matter of right *and* Congress considered whether to make such a program the injured's exclusive remedy. Knowing the importance of the tool of discovery to explaining how vaccine injuries occur, why would Congress intend to entirely take that tool away from injured children? The answer is it wouldn't.

When asked by Representative Henry A. Waxman why families needed to retain the option to litigate outside the program, Jeffrey Schwartz, co-founder of the National Vaccine Information Center and former counsel for the House of Representatives Health and Environment Subcommittee of the Energy and

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authors compared internal Merck documents regarding Vioxx with published studies of the drug's safety. *See* Bruce M. Psaty & Richard A. Kronmal, *Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment: A Case Study Based on Documents from Rofecoxib Litigation*, 299 J. Am. Med. Ass'n 1813, 1813-14 (2008). The authors concluded that Merck's internal data showed a significant increase in mortality while the published articles did not, a difference in reporting that the authors called "striking." *Id.* at 1813, 1816. The JAMA article noted that Merck's mortality analyses were "neither provided to the FDA nor made public in a timely fashion" and called for new approaches to the conduct, oversight, and reporting of industry sponsored drug trials. *Id.* at 1813, 1817.

Commerce Committee, the Subcommittee that drafted the Vaccine Act, replied, "Do you want to remove the mechanism to find the truth? These lawsuits are discovering things that ought to cause the Congress concern." *Hearings on H.R. 5810*, *supra*, at 115. The information revealed by discovery did cause Congress concern over the safety of vaccines, and it inspired Congress to keep the tort option available as a safety incentive. *See Hearing on S. 827*, pt. 1, *supra*, at 16-17 (statement of Sen. Robert T. Stafford).

B. Requiring the information that only the vaccine manufacturer possesses, Mrs. DeLoatch requested discovery from Merck, which discovery was denied pursuant to the restraints of the Vaccine Program.

Mrs. DeLoatch attempted to obtain Merck's records for use by her medical experts in the Vaccine Program. *See DeLoatch v. Sec'y of Health & Human Servs.*, slip op. at 1. While not the speediest approach, it was Mrs. DeLoatch's only choice and her only hope. Mrs. DeLoatch requested a subpoena seeking just two categories of documents from Merck regarding deaths related to the Gardasil vaccine.[6]

Merck objected to the subpoena and moved to quash it. *Id.* at 1-2. In its objection, Merck did not argue that the request was unduly burdensome but

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[6] Specifically, the subpoena requested:

1. Any reports of sudden death temporally related to Gardasil vaccination (please redact any patient identifying information).
2. Any papers, reports, or memoranda discussing a possible biological mechanism by which the Gardasil vaccine could cause or trigger sudden death.

DeLoatch v. Sec'y of Health & Human Servs., slip op. at 2 n.2.

instead argued that Mrs. DeLoatch had not satisfied the standard for discovery. *Id.* at 2.

In light of Merck's objection and the limited discovery permitted within the Vaccine Program, Mrs. DeLoatch faced an uphill battle in her quest for the documents that could explain how her daughter died. The Special Master ultimately agreed with Merck and quashed the subpoena. *Id.* at 9.

C. After quashing her subpoena to Merck, the Special Master suggested Mrs. DeLoatch leave the Vaccine Program and file suit against Merck.

Acknowledging Mrs. DeLoatch's dilemma in obtaining the information required for her claim, the Special Master outlined two potential consequences of his ruling. *See DeLoatch v. Sec'y of Health & Human Servs.*, slip op. at 8. First, the Special Master explained, Mrs. DeLoatch's experts "may require a relatively lengthy amount of time to develop a theory to explain how Gardasil can cause a person's death." *Id.* The Special Master, most graciously, indicated his willingness to grant Mrs. DeLoatch this time provided her experts were continuing to make progress in developing a theory. *Id.* Unfortunately for Mrs. DeLoatch, it is unlikely that literature on the adverse effects of Gardasil will be released in time to assist her case.

The second potential consequence set forth by the Special Master was that Mrs. DeLoatch may decide to leave the Vaccine Program and pursue an action against Merck in state or federal court. *Id.* In this scenario, the Special Master explained that Mrs. DeLoatch would be able to present a similar discovery request to Merck. *Id.* Thus, the Special Master stated, "Under this scenario, Merck's successful mo-

tion to quash the subpoena in this action may result in it being named as a defendant in a lawsuit over Gardasil. Merck is aware of this possibility." *Id.* at 9 (citing to oral argument on Merck's motion). Citing to the instant case of *Bruesewitz v. Wyeth*, the Special Master informed the parties that "Congress expressly left open the possibilities for some lawsuits against vaccine manufacturers." *Id.*

Thus, the Vaccine Court has informed Mrs. DeLoatch that in her case justice cannot be swift. For Mrs. DeLoatch, the type of evidence needed to satisfy even the streamlined standards of the Vaccine Program cannot be obtained within the discovery restrictions of the Vaccine Program. Ironically, Mrs. DeLoatch's case has been delayed, possibly derailed, by discovery restrictions that were designed to ensure the speedy resolution of vaccine injury compensation claims.

In this case, the Special Master advised the parties of Mrs. DeLoatch's right to opt out of the Vaccine Program and sue Merck under a traditional tort theory for the death of her healthy daughter after her receipt of the Gardasil vaccine. *Id.* at 8-9. A Special Master of the Vaccine Program, in essence, has informed Mrs. DeLoatch that the Vaccine Program may not be the appropriate forum for her. It may not be the best means by which to demonstrate the cause of her daughter's death. Mrs. DeLoatch has been told that the Vaccine Program can neither provide her with the discovery her case requires nor deliver the swift justice that Congress intended for the Program. Mrs. DeLoatch has been advised that she may be better off in state or federal court.

Most importantly, Mrs. DeLoatch has been informed by the Vaccine Court that leaving the Vaccine

Program and filing suit against Merck is an option available to her. *Id.* The Vaccine Court has expressly acknowledged that Congress left open the possibility of suits against vaccine manufacturers. *Id.* The Vaccine Court has informed Mrs. DeLoatch that she may need to sue Merck to demonstrate how the Gardasil vaccine contributed to her daughter's death. *Id.*

D. The practical effect of the Third Circuit's opinion in the instant case is to deny justice to petitioners in the Vaccine Program whose cases cannot be fully litigated given the restrictions built into the Program.

Of course, Mrs. DeLoatch may feel this is an option available to her, and the Vaccine Court itself may believe this is an option available to Mrs. DeLoatch, but there can be little doubt that, should Mrs. DeLoatch opt out of the Vaccine Program and file suit, Merck would immediately seek to dismiss Mrs. DeLoatch's action based upon the Third Circuit's opinion in the instant case.[7] Once again raising the battle cry that the Vaccine Act was intended to protect vaccine manufacturers from litigation, Merck would likely argue that Mrs. DeLoatch has no right to obtain discovery or even to proceed against Merck in federal or state court, as suggested by the Special Master.[8] Should the vaccine manufacturer prevail in

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[7] In stating her tort claim, Mrs. DeLoatch would plead that her daughter's death was caused by the defective design of the Gardasil vaccine. She would show that Moshella's death could have been avoided through a safer design.

[8] Vaccine manufacturers may argue that the Vaccine Act still permits manufacturing defect claims and failure to warn claims even in light of the Third Circuit's interpretation of the Act as preempting design defect claims. However, in practice, manufacturers rely on precedents that all but subsume manufactur-

this argument, the consequences for Mrs. DeLoatch would be tragic. For Mrs. DeLoatch, there would be no justice.[9]

The Vaccine Act was designed to provide swift and simple justice. However, to achieve this justice, the Vaccine Program could not be administered in the same manner as traditional tort litigation. Restrictions on discovery, evidence, and motion practices were employed to speed up the process. Congress and those persons who contributed to the drafting of the Act, through years of Congressional hearings and effort, realized that the restrictions needed to supply swift and simple justice would not mete out justice in all situations. The Vaccine Act was not envisioned as providing a one size fits all form of resolution. Given the limits of the Act, the Vaccine Program cannot provide satisfactory relief for every family of a vaccine-injured child. Mrs. DeLoatch's case provides a concrete example of this principle.

Time and time again, as the Vaccine Act was debated, vaccine manufacturers demanded that the Vaccine Program be the exclusive remedy available to the vaccine injured. *See Hearings on H.R. 5810, supra*, at 230 (statement of Robert Johnson, Presi-

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ing defect claims and failure to warn claims into design defect claims. *See Cronin v. J.B.E. Olson Corp.*, 501 P.2d 1153, 1163 (Cal. 1972) ("[A] distinction between manufacture and design defects is not tenable. ... We wish to avoid providing such a battleground for clever counsel.").

[9] This Court has rejected the application of an analysis that would render a "humane legislative plan" a "delusive remedy." *Urie v. Thompson*, 337 U.S. 163, 168-70 (1949). In *Urie*, this Court found that such an analysis could "only serve to thwart the congressional purpose." *Id.* Similarly, it cannot be justly supposed that Congress intended the Vaccine Act to be a delusive promise of a remedy for petitioners like Mrs. DeLoatch.

dent, Lederle Laboratories); *Hearing on S. 827*, pt. 1, *supra*, at 240-41, 265, 274-75 (statements of Robert Johnson, President, Lederle Laboratories, and David Williams, Vice President and General Manager, Connaught Laboratories). Time and time again, parents and members of Congress alike insisted that the alternative of a traditional tort suit remain available for the families of the injured. *See Hearings on H.R. 5810*, *supra*, at 115-16 (statement of Jeffrey H. Schwartz); *Hearing on S. 827*, pt. 1, *supra*, at 392 (statements of Jeffrey H. Schwartz and Barbara Loe Fisher); *Hearing on S. 827 Before the S. Comm. on Labor & Human Res.*, pt. 2, 99th Cong. 1-2 (1986) (opening statement of Sen. Robert T. Stafford). During those debates, the vaccine manufacturers insisted that allowing families the right to choose between the compensation program and an action sounding in tort would result in no relief for vaccine manufacturers. *See Hearing on S. 827*, pt. 1, *supra*, at 250, 274-75 (statements of Robert Johnson, President, Lederle Laboratories, and David Williams, Vice President and General Manager, Connaught Laboratories); *Hearing on H.R. 1780, H.R. 4777, and H.R. 5184*, *supra*, at 217 (questioning by Rep. Henry A. Waxman). Despite testimony from parent groups to the contrary, manufacturers insisted that parents would not choose the Vaccine Program and, instead, manufacturers would be beset with vaccine suits. *Id.*

In briefing before this Court, the vaccine manufacturer has again raised the specter of state and federal courts being flooded with vaccine cases. *See* Brief in Response to Petition for a Writ of Certiorari at 2, 17-18, 22, *Bruesewitz v. Wyeth, Inc.*, No. 09-152 (U.S. filed Oct. 7, 2009). This scare tactic did not prove to be true in the 1980s, nor would it be true today. The

amicus curiae on this brief, the Petitioners Bar, has, through its members, been representing petitioners in the Vaccine Program since the Program's inception. As a group, these *amici* can recall less than 12 instances, including the present case, in which a petitioner with a claim in the Vaccine Program has opted out of the Program and then pursued a state or federal court claim against a vaccine manufacturer. While these *amici* have always understood the Vaccine Act and Congress's intent to permit petitioners to opt out of the Program to pursue design defect claims against manufacturers, they have witnessed their clients and other petitioners actually opt out only a handful of times.

Via the vaccine manufacturer's interpretation of the Vaccine Act, petitioners such as Mrs. DeLoatch are simply out of luck. It is their contention that the Act was designed to protect them from entanglement within the Vaccine Program even where such entanglement is not burdensome. They further contend that the Act was designed to protect them from entanglement in suits outside of the Program. Such contentions ignore the intent of the creators of the Program.[10] Cognizant of the limits in the compensation program it established, did Congress intend for families like Mrs. DeLoatch and her daughter, Moshella, to be left without a route to justice?

It is for the children and for petitioners such as Mrs. DeLoatch who have lost their children that

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[10] The sponsors of the Vaccine Act did not intend to prevent claimants like Mrs. DeLoatch from having their day in court. According to Representative Henry A. Waxman, "If an injury is the result of a bad vaccine or *one inadequately researched* or warned of, then the courts could still make awards." 132 Cong. Rec. H9943-02 (daily ed. Oct. 14, 1986) (emphasis supplied).

Congress created the Vaccine Program. It is for petitioners such as Mrs. DeLoatch and the other five families of young women who died shortly after receiving the Gardasil vaccine, as well as other families that may not receive a full resolution in the Vaccine Program, that Congress chose *not* to make the Vaccine Program the exclusive remedy available for families of the vaccine-injured. There is a purpose for the statutory language that permits a petitioner to leave the Program and file suit against a manufacturer. That purpose is to provide justice for *all* families of vaccine-injured children.

If this Court closes the courthouse doors to petitioners like Mrs. DeLoatch, they will not receive the swift justice promised by Congress. They will not receive the slower justice of a tort claim, also promised by Congress. These petitioners, families of the vaccine-injured, will be denied justice.

CONCLUSION

For the foregoing reasons, the judgment below should be reversed.

Respectfully submitted,

JENNIFER ANNE GORE MAGLIO
Counsel of Record
MAGLIO CHRISTOPHER TOALE
& PITTS LAW FIRM
1751 Mound Street
Second Floor
Sarasota, Florida 34236
(941) 952-5242
(jmaglio@mctplaw.com)

PROFESSOR PETER H. MEYERS
DIRECTOR, VACCINE INJURY CLINIC
THE GEORGE WASHINGTON
UNIVERSITY LAW SCHOOL
2000 G Street, N.W.
Washington, D.C. 20052
(202) 994-7463

June 1, 2010

AMICUS CURIAE BRIEF

No. 09-152

IN THE

Supreme Court of the United States

RUSSELL BRUESEWITZ, ET AL.,

Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, ET AL.,

Respondent.

On Writ of Certiorari
To the United States Court of Appeals
For the Third Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

Daniel J. Popeo
Cory L. Andrews
Counsel of Record
WASHINGTON LEGAL
FOUNDATION
2009 Mass. Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org

Date: July 30, 2010

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

As part of a comprehensive scheme to shield vaccine manufacturers from the costs and risks of product liability litigation, the National Childhood Vaccine Injury Act of 1986 provides that "[n]o vaccine manufacturer shall be liable in a civil action" if the plaintiff's injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Does Section 22(b)(1) expressly preempt all state-law claims against a vaccine manufacturer based on alleged defects in the design of a vaccine subject to the Act?

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit, public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. WLF regularly publishes monographs and other publications on these and related topics. In particular, WLF has regularly appeared as *amicus curiae* before this and numerous other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek to regulate the same activity. *See, e.g., Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000).

WLF is particularly concerned that individual freedom, the American economy, and the public health and welfare suffer whenever state law, especially state tort law, imposes on the vaccine industry additional costs and an unnecessary layer of regulation, both of which frustrate the objectives and operation of specific congressional schemes, such as (in this case) the National Childhood Vaccine Injury Act (the Vaccine Act).

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief.

At issue here is whether Congress intended to preempt Petitioners' design defect claims. WLF agrees with Respondent and the U.S. Court of Appeals for the Third Circuit that Congress's preemptive intent under the facts of this case is expressly manifested by the Vaccine Act's preemption provision, 42 U.S.C. § 300aa-22(b)(1). WLF writes separately to emphasize that a contrary statutory interpretation undermines the important public policy undergirding the Vaccine Act's enactment–namely, the facilitation and stabilization of a robust childhood vaccine market.

WLF has no direct interest, financial or otherwise, in the outcome of this case. WLF submits this brief solely to further the public's interest in the important preemption issues raised by this case. All parties have consented to the filing of this brief by lodging their consents in the Court's docket.

STATEMENT OF THE CASE

This case raises important issues about the continued viability of a national childhood vaccine market, the preservation of which is a central aim of the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act), 42 U.S.C. §§ 300aa-1 *et seq*. In their efforts to expose the nation's vaccine manufacturers to state-court tort liability for alleged design defects, Petitioners ignore both the market realities and the important public policy considerations that initially prompted Congress to pass the Vaccine Act.

In response to an explosion in vaccine litigation costs that seriously threatened to destabilize the nation's vaccine market, Congress passed the Vaccine Act, which

established a national, comprehensive, no-fault compensation system for vaccine-related injuries. In order to protect vaccine manufacturers from the same kind of burdensome litigation that had already driven many manufacturers from the market, Congress included an express preemption provision in Section 22(b)(1) of the Vaccine Act to limit the scope of damage claims that can be brought against a vaccine manufacturer. Section 22(b)(1) provides in full:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1). This provision bars state-law tort liability against childhood vaccine manufacturers for all possible claims except those alleging a manufacturing defect or a failure to warn.

Although preempting all state-law tort claims (other than manufacturing defect and failure-to-warn claims), the Vaccine Act provides a generous administrative compensation scheme that is funded by Congressional appropriation and an excise tax on vaccines. Under this no-fault compensation scheme, claimants are relieved from the obligation to prove fault–they need establish only an injury that occurred within the time frame specified in the federal "vaccine table" or prove a vaccine-related injury. 42 U.S.C. §

300aa-11. A successful claimant may recover unlimited medical expenses, medical care, lost earnings, and up to $250,000 for pain and suffering. *Id.* at § 300aa-15(a). Regardless of whether they receive compensation, claimants may recover attorney's fees and costs. *Id.* at § 300aa-15(e).

In 1995, Russell and Robalee Bruesewitz (the Bruesewitzes) petitioned the Vaccine Court to compensate their daughter's injuries, which they alleged were caused by a Diptheria, Tetanus, and Pertussis (DTP) vaccination administered in 1992. Pet. App. at A-8. After a full evidentiary hearing, the Vaccine Court dismissed with prejudice the Bruesewitzes' petition for failure to establish any causal link between the administered DTP vaccine and their daughter's injuries. *Id.* at A-9.

Rather than appeal their dismissal to the Court of Federal Claims, the Bruesewitzes rejected the judgment of the Vaccine Court and filed a products liability suit against Wyeth in the Philadelphia County Court of Common Pleas. *Id.* On the basis of diversity jurisdiction, Wyeth removed the suit to the United States District Court for the Eastern District of Pennsylvania. *Id.* The Bruesewitzes' complaint sought in part to recover damages in strict liability for an alleged design defect in the DTP vaccine. *Id.*

Following extensive discovery, Wyeth moved for summary judgment in part on the grounds that Section 22(b)(1) of the Vaccine Act preempts all design defect claims arising from a vaccine-related injury or death. The district court invited, *sua sponte*, the U.S. Food and Drug Administration (FDA) and the U.S. Department of

Health and Human Services (HHS) to submit an *amicus* brief on the preemption question. *Id.* at A-112. In a letter to the district court, both the FDA and HHS responded that they had no official view on preemption because neither is a party to a civil action commenced after a claimant exhausts the administrative compensation process, nor do they administer any of the statutory provisions that govern such actions. *Id.* at A-107-09.

Adopting the statutory interpretation urged by Wyeth, the district court held that Section 22(b)(1) expressly preempted the Bruesewitzes' design defect claim. *Id.* at A-87. On appeal, the U.S. Court of Appeals for the Third Circuit affirmed. Recognizing that the statutory text, structure, and legislative history of the Vaccine Act evidenced "a 'clear and manifest' expression of congressional intent" to preempt all design defect claims, the appeals court held that the Bruesewitzes' design defect claim was preempted by Section 22(b)(1). *Id.* at A-30. In doing so, the Third Circuit panel expressly rejected the construction of the Vaccine Act urged by the Bruesewitzes, concluding that allowing plaintiffs to bring design defect claims against vaccine manufacturers would yield the "very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act." *Id.* at A-36.

SUMMARY OF ARGUMENT

The Bruesewitzes urge this Court to construe the Vaccine Act in a way that ignores both the unique and vital role vaccines have historically played in safeguarding the public health, as well as the national

health emergency that arose in the 1980s due to the very patchwork of state tort liability that the Bruesewitzes now seek to revive. At issue is whether Congress intended to preempt the Bruesewitzes' design defect claims. As Respondent ably demonstrates, and the U.S. Court of Appeals for the Third Circuit correctly found, Congress's preemptive intent under the facts of this case is expressly manifested by the Vaccine Act's preemption provision, 42 U.S.C. § 300aa-22(b)(1). But a contrary statutory interpretation would also undermine the important public policy undergirding the Vaccine Act's enactment–namely, the facilitation and stabilization of a robust childhood vaccine market.

Since their widespread development and use over a century ago, childhood vaccines have enjoyed remarkable success. Vaccinations have saved countless lives and further prolonged the life expectancy of millions of people. Perhaps more than any other medical innovation, vaccines have played a decisive role in enhancing the quality of life of people in the United States. Likewise, childhood vaccines have enjoyed overwhelming success in reducing the incidence of communicable diseases. Physicians and other public health experts widely champion vaccines as the single most effective means of disease prevention. Yet, notwithstanding their immense benefit to the vast majority of recipients, vaccines are not immune from the law of unintended consequences. As is true for any prescription drug or pharmaceutical product on the market, childhood vaccines may pose adverse side effects to a small fraction of children who receive them.

Following an escalation in media coverage of vaccine-related injuries in the 1970s, more and more

allegedly injured individuals began bringing civil suits against vaccine manufacturers and administrators. In fact, between 1980 and 1986, plaintiffs sought claims against vaccine manufacturers in excess of $3.5 billion. During this time, juries issued increasingly extravagant punitive damages awards for plaintiffs, even in cases where no conclusive scientific evidence could causally link the administered vaccine to the plaintiff's injury.

Vaccine manufacturers responded to the increased threat of exorbitant litigation costs by exiting the marketplace, which threatened to leave children vulnerable to many preventable diseases. In four short years, the cost for a dose of the DTP vaccine increased from only $0.11 in 1982 to $11.40 in 1986, with approximately $8.00 of that price strictly allocated to liability insurance. By 1985, only four manufacturers still produced the childhood vaccines that states required for public school immunizations. By the end of the 1980s, ten of the thirteen companies manufacturing crucial childhood vaccines had exited the marketplace. Crippled by the explosive costs of surging vaccine-related litigation, vaccine manufacturers became both unable and unwilling to meet the nation's childhood vaccine needs.

In direct response to the nation's emerging vaccine crisis, a national consensus quickly developed in favor of creating a no-fault reimbursement regime to shield manufacturers from liability, which in turn would help to promote the continued, long-term viability of a national vaccine market. At the same time, even victims of vaccine-related injuries criticized the high cost of litigation necessary to obtain an adequate recovery, which could remain uncertain and elusive under a

traditional tort-law civil justice system. It was against this backdrop of vaccine shortages and out-of-control costs that Congress passed the National Childhood Vaccine Injury Act of 1986, which established a national, comprehensive, no-fault compensation system for vaccine-related injuries.

In considering the Vaccine Act, Congress found that "[t]he number of childhood vaccine manufacturers [had] declined significantly," while the remaining few were forced "to question their continued participation in the vaccine market." H.R. Rep. No 908, 99th Cong., 2d Sess. 7 (1986). Congress specifically recognized that the "withdrawal of even a[nother] single manufacturer would present a very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." *Id.* In order to protect vaccine manufacturers from the same kind of burdensome litigation that had already driven many manufacturers from the market, Congress included an express preemption provision in Section 22(b)(1) to limit the scope of damage claims that can be brought against a vaccine manufacturer. This preemption provision, by shielding vaccine manufacturers from design defect liability, is the linchpin of the Vaccine Act.

The contrary interpretation of the Vaccine Act urged by the Bruesewitzes would completely undermine one of the principal policy considerations that influenced Congress's decision to pass the Vaccine Act. Allowing a disappointed vaccine claimant who lost in the Vaccine Court to then seek compensation for design defects via civil tort litigation would exacerbate, not remedy, the burden of litigation and the threat of large and

unpredictable jury awards against vaccine manufacturers. Nor would it do anything to help to control the skyrocketing costs that would result from extravagant civil jury awards. In weighing the costs and benefits of a robust vaccine market, Congress elected for uniform administrative regulation over a patchwork of state tort law.

ARGUMENT

I. PRIOR TO ENACTMENT OF THE VACCINE ACT, AN EXPLOSION IN LITIGATION AGAINST VACCINE MANUFACTURERS CAUSED A NATIONAL VACCINE CRISIS

Since their widespread development and use over a century ago, childhood vaccines have enjoyed remarkable success. Vaccinations have saved countless lives and further prolonged the life expectancy of millions of people. Perhaps more than any other medical innovation, vaccines have played a decisive role in enhancing the quality of life of people in the United States, where vaccines provide "an extremely cost-effective technology for dealing with killer diseases, saving lives, and averting millions of dollars of potential health spending." Patricia M. Danzon, *et al.*, *Vaccine Supply: A Cross-National Persepctive*, 24 Health Affairs 706 (May 27, 2005). During the 20th century, for example, "the lifespan of Americans increased by 30 years–mostly because of vaccines." Paul A. Offit, *Lawsuits Won't Stop Pandemics*, Wall St. J., Dec. 1, 2005, at A16.

Likewise, childhood vaccines have enjoyed overwhelming success in reducing the incidence of

communicable diseases. Physicians and other public health experts widely champion vaccines as the "single most effective [means of] health prevention." Elizabeth A. Breen, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 Wm. & Mary L. Rev. 309, 311-12 (1999) (citation omitted). Indeed, "[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. No 908, 99th Cong., 2d Sess. 4 (1986). According to the U. S. General Accountability Office (GAO), vaccination in the United States has resulted in a ninety-five percent reduction in the total number of people who contract "vaccine-preventable diseases." GAO, *Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily*, at 1 (1999). The introduction of widespread vaccinations saw the number of children afflicted by polio decrease from over 15,000 each year to zero. *See* Offit, *supra* at A16.

As early as 1905, this Court acknowledged the vital role vaccines play in safeguarding America's public health. In *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the Court upheld a local ordinance requiring mandatory smallpox vaccinations for all residents. Writing for the Court, Justice Harlan emphasized that because "vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was–perhaps or possibly–not the best for either children or adults." *Jacobson*, 197 U.S. at 35. Following the Court's ruling in *Jacobson*, other states

quickly followed suit, and widespread mandatory vaccine use was implemented across the country. In fact, "[a]ll fifty states and the District of Columbia have immunization requirements for children that must be met before they may attend public school." Breen, *supra* at 311.

Notwithstanding their immense benefit to the vast majority of recipients, vaccines are not immune from the law of unintended consequences. As is true for any prescription drug or pharmaceutical product on the market, childhood vaccines may give rise to adverse side effects among a small fraction of children who receive them. As the number of doses of vaccines administered has risen dramatically, so too has the number of reported but unintentional side effects. *See, e.g.*, Randall B. Keiser, *Deja Vu All Over Again? The National Childhood Vaccine Injury Compensation Act of 1986*, 47 Food & Drug L.J. 15, 15 (1992). Adverse reactions can vary from "local reactions at the injection sight [sic], such as redness or swelling, to more systemic reactions such as convulsions or very high fevers." *Id.* at 16.

Of course, it is virtually impossible to predict precisely what reaction, if any, a child will have to a given vaccine. *See* H.R. Rep. No. 99-908, at 6 (1986) (confirming that there is no "reaction-free" vaccine available, and that it is "not always possible to predict" which children will react adversely or how severe those reactions will be). Ultimately, only a small percentage of children who are vaccinated will ever suffer a serious injury. *See, e.g.*, Mary Beth Neraas, *Comment, The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 Wash. L. Rev. 149, 150 (1988) (explaining that only a "tiny fraction" of

children will suffer from a significant adverse reaction to a vaccination). And the overwhelming majority of adverse reactions to vaccines are found to result from the "unavoidable cost of mass inoculation" and are not the fault of the vaccine manufacturer. *Id.* at 150-51.

With millions of vaccinations administered in the United States each and every year, the number of reported cases of adverse reactions resulting in vaccine-related injuries grew. By 1976, highly publicized reports in the media only further sensationalized the issue of vaccination, at a time when "many people reportedly contracted Gullain-Barré Syndrome after being vaccinated against the swine flu, an epidemic that never materialized." Kathy Koch, *Vaccine Controversies: Are Today's Vaccines Safe Enough?*, 10 Cong. Q. Researcher 641, 645 (2000). A 1982 television documentary entitled "DPT Vaccine Roulette" further stoked fears about the dangers of the DTP vaccine by highlighting the stories of children who suffered neurological disabilities after receiving their DTP vaccinations. *Id.*; *see also* Breen, *supra* at 315.

In the wake of escalating media coverage, more and more allegedly injured individuals began bringing civil suits against vaccine manufacturers and administrators. By the 1980s, the prospect of obtaining a lucrative jury verdict led a growing number of civil plaintiffs to file "ever larger claims against [vaccine] manufacturers." Derry Ridgway, *No-Fault Vaccine Insurance: Lessons From the National Vaccine Injury Compensation Program*, 24 J. Health Pol. Pol'y & L. 59, 60 (1999). In fact, between 1980 and 1986, plaintiffs sought claims in excess of $3.5 billion, and many observers predicted potentially unlimited liability for

vaccine manufacturers in the future. *Id.* at 60-61. During this time, juries issued increasingly extravagant punitive damages awards even in cases where no conclusive scientific evidence could causally link the administered vaccine to the plaintiff's injury. Elissa Levy, *The Health Act's FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 Fordham L. Rev. 2425, 2431 (1006).

As a consequence of the unpredictable nature of tort liability, which typically varied widely from state to state, many pharmaceutical companies simply stopped manufacturing and distributing vaccines. *See* Neraas, *supra* at 152. Indeed, "exposure to large damage awards provided the economic justification for companies to stop research and production." Paula Jacobi, *Pharmaceutical Tort Liability: A Justifiable Nemesis to Drug Innovation and Access?*, 38 J. Marshall L. Rev. 987, 989 (2005). As a result, vaccine prices skyrocketed. For example, in four short years, the cost for a dose of the DTP vaccine increased from only $0.11 in 1982 to $11.40 in 1986, with approximately $8.00 of that price explicitly allocated to liability insurance. John K. Inglehart, *Health Policy Report: Compensating Children with Vaccine-Related Injuries*, 316 New Eng. J. Med. 1283, 1286 (1987).

Such increased exposure to tort liability quickly forced the few remaining vaccine manufacturers to dedicate "an ever larger percentage of revenues from vaccine sales to the costs of insurance and of defending against potential liability." Deborah J. LaFetra, *Freedom, Responsibility, and Risk: Fundamental Principles Supporting Tort Reform*, 36 Ind. L. Rev. 645, 650 (2003). By 1985, only four manufacturers still produced the childhood vaccines that states required for

public school immunizations. *See* Neraas, *supra* at 152. By the end of the 1980s, ten of the thirteen companies manufacturing crucial childhood vaccines had exited the marketplace. *See* Lafetra, *supra* at 650. Crippled by the explosive costs of surging vaccine-related litigation, vaccine manufacturers became both unable and unwilling to meet the nation's childhood vaccine needs. It was against this backdrop of vaccine shortages and out-of-control costs that Congress passed the Vaccine Act.

II. IN DIRECT RESPONSE TO THE NATIONAL VACCINE CRISIS, CONGRESS PASSED THE VACCINE ACT TO HELP STABILIZE THE NATION'S VACCINE MARKET

As early as 1974, in the case of *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974), Judge John Minor Wisdom suggested (in dicta) that compensation for unavoidable vaccine-related injuries should be borne primarily by price increases passed on to the public, without a finding of negligence on the part of manufacturers. This proposal was later reinforced in influential peer-reviewed pediatric journals, which helped to rally policy makers behind a no-fault liability scheme for vaccine-related injuries. Ridgway, *supra* at 41.

In direct response to the nation's emerging vaccine crisis, a national consensus quickly developed in favor of creating a no-fault reimbursement regime to shield manufacturers from liability, which in turn would help to promote the continued, long-term viability of a national vaccine market. At the same time, even victims of vaccine-related injuries criticized the high cost of

litigation necessary to obtain an adequate recovery, which could remain uncertain and elusive under a traditional tort-law civil justice system. Most experts agreed that any viable no-fault compensation scheme would need to remedy each of these concerns.

In 1986, Congress enacted the Vaccine Act, which established a national, comprehensive, no-fault compensation system for vaccine-related injuries. Designed to encourage "development and distribution of vaccines that will further enhance the public health," the Vaccine Act establishes the National Vaccine Injury Compensation Program, which offers monetary awards to those who suffer injuries causally linked to specific childhood vaccines. H.R. Rep. No. 99-908, at 7 (1986). In order to protect vaccine manufacturers from the same kind of burdensome litigation that had already driven many manufacturers from the market, Congress included an express preemption provision in Section 22(b)(1) to limit the scope of damage claims that can be brought against a vaccine manufacturer. This provision bars state-law tort liability against vaccine manufacturers for all claims except those alleging manufacturing defect and failure to warn. *See* 42 U.S.C. § 300aa-22(b)(1).

While preempting all state-law tort claims (other than manufacturing defect and failure-to-warn claims), the Vaccine Act also provides a generous administrative compensation scheme that is funded by Congressional appropriations and an excise tax on vaccines. *Id.* at § 300aa-10 to 300aa-19; 26 U.S.C. § 4131. Under this no-fault compensation scheme, claimants are relieved from the obligation to prove fault–they only need establish an injury that occurred within the time frame specified in

the federal "vaccine table" or else prove a vaccine-related injury. 42 U.S.C. § 300aa-11. A successful claimant may recover unlimited medical expenses, medical care, lost earnings, and up to $250,000 for pain and suffering. *Id.* at § 300aa-15(a). And, regardless of whether they receive compensation, claimants may recover attorney's fees and costs. *Id.* at § 300aa-15(e).

Although not dispositive, it is often useful to consult a statute's legislative history to determine the goals articulated by members of Congress while debating the proposed statute. As this Court has recently recognized, historical statements by those who drafted or voted for a law are relevant "not because they reflect the general understanding of the disputed terms, but because the legislators who heard or read those statements presumably voted with that understanding." *District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008). Examination of the Congressional Record makes clear that those members of Congress who debated the Vaccine Act legislation in 1986 believed they were enacting a law aimed at addressing "two overriding concerns": (1) "the inadequacy–from both the perspective of vaccine-injured persons as well as vaccine manufacturers–of [a tort-based] approach to compensating those who have been damaged by a vaccine," and (2) "the instability and unpredictability of the childhood vaccine market" arising from the manufacturers' increased exposure to tort liability. H.R. Rep. No. 99-908, at 7 (1986).

In considering the Vaccine Act, Congress found that "[t]he number of childhood vaccine manufacturers [had] declined significantly, while the remaining few were forced "to question their continued participation in

the vaccine market." *Id.* at 4, 7. Congress specifically recognized that the "withdrawal of even a[nother] single manufacturer would present a very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases." *Id*

Most relevant here, the Vaccine Act's preemption of state tort law under Section 22(b)(1) is the linchpin by which Congress sought to allay the vaccine industry's fears of "instability and unpredictability of the childhood vaccine market" due to abusive tort liability. *See, e.g., Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994) ("[A]n important federal purpose of the Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market."); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007) (confirming that the Vaccine Act was enacted "to prevent manufacturers from leaving vaccine production or significantly increasing prices, while at the same time compensat[ing] victims of vaccine related injuries quickly").

In weighing the costs and benefits of a robust vaccine market, Congress elected for uniform administrative regulation over a patchwork of state tort law. In the context of childhood vaccines, a national preemption scheme is absolutely crucial because the risk analysis for vaccines involves a "forward-looking" assessment of future liability for future conduct before any injury occurs. Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 Okla. L. Rev. 135, 135-136 (2005). And by preempting tort law claims, the Vaccine Act has succeeded in

promoting a robust national vaccine market. Indeed, since the Vaccine Act took effect over 20 years ago, more than 20 new childhood vaccines have obtained FDA approval and been introduced to the market. *See* Resp. Br. at 15-16.

In sum, the interpretation of the Vaccine Act urged by the Bruesewitzes would completely undermine one of the principal policy considerations that influenced Congress's decision to pass the Act. Allowing a disappointed vaccine claimant who lost in the Vaccine Court to then seek full compensation via civil tort litigation would exacerbate, not remedy, the burden of litigation and the threat of large and unpredictable jury awards against vaccine manufacturers. Nor would it do anything to help to control the skyrocketing costs that would result from extravagant civil jury awards. As this Court has previously acknowledged in the related area of medical devices, "[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008). Nowhere is this truer than in the context of childhood vaccines, where, "even though vaccines themselves cause a small number of serious injuries or deaths, their widespread use dramatically reduces fatalities." *Schafer*, 20 F.3d at 4.

AMICUS CURIAE BRIEF

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Supreme Court of the United States

RUSSELL BRUESEWITZ, *et al.*,

Petitioners,

v.

WYETH, INC., fka WYETH LABORATORIES, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF AMICUS CURIAE MARGUERITE WILLNER IN SUPPORT OF PETITIONERS

ANN M. LIPTON
Counsel of Record

SALVATORE J. GRAZIANO
BERNSTEIN LITOWITZ BERGER
& GROSSMANN LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 554-1400
ann@blbglaw.com

Counsel to Amicus Curiae Marguerite Willner

230243

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

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INTEREST OF AMICUS CURIAE[1]

Marguerite Willner is a recognized expert in federal vaccine policy. In 2004, at the recommendation of Senator John Warner, Ms. Willner was appointed by the Secretary of the Department of Health and Human Services (HHS) to the Advisory Commission on Childhood Vaccines (ACCV) to represent the public at large.[2] The ACCV was established by Congress to advise the Secretary on matters related to the implementation of the National Vaccine Injury Compensation Program. She was elected ACCV Vice-Chair in 2005 and completed her term in 2007.

During this period, Ms. Willner served as the ACCV liaison to and *ex officio* member of the National Vaccine Advisory Committee (NVAC), participating in the Subcommittee for Vaccine Safety and the NVAC Public Engagement Project. Ms. Willner has also been invited to present her views on expert panels at the 2005 and 2008 Federal Judicial Conferences as well as an expert panel convened last summer by the NVAC Vaccine Safety Working Group.

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus curiae, and her counsel, made a monetary contribution to its preparation or submission. Letters from the parties consenting to the filing of all amici briefs have been filed with the Clerk of the Court.

[2] Although some members are required to have vaccine-injured children, Ms. Willner does not.

This brief is submitted in support of Petitioners to describe the shortcomings of the existing vaccine safety infrastructure and to highlight the critical role that civil actions play in discovering if a vaccine is "unavoidably unsafe," compensating those who suffer avoidable injuries, and deterring those who would manufacture anything less than the safest vaccine feasible.

SUMMARY OF ARGUMENT

Although vaccines are a critical component of public health care, research on vaccine safety remains flawed and incomplete. This lack of information about vaccines' safety profile stems in part from the difficulties inherent in evaluating safety in large, diverse populations. Because vaccines are administered to healthy people and not for their therapeutic benefit, medical ethics require that they be extremely safe; however, clinical trials do not involve enough participants to determine whether a vaccine is likely to cause adverse events in a small number of patients. Thus, vaccines can only be fully evaluated once they are in general use. Even then, regulators may not be able to determine whether temporally-associated adverse events are caused by the vaccine.

In recognition of the uncertain state of medical research and the inherent justice of compensating vaccine-injured persons who have sacrificed their own health in service of the greater public benefit of widespread inoculation, in 1986 Congress passed the National Childhood Vaccine Injury Act ("NCVIA"). The NCVIA included many measures intended to encourage

vaccine research and the development of safer vaccines, and created a no-fault compensation system to quickly provide money damages to vaccine-injured persons. However, NCVIA was never intended to supplant incentives that state tort law provides to manufacturers to develop safer versions of their products. Most critically, the compensation system was not designed for determinations of causation, and, in fact, petitioners within the compensation system are denied access to basic discovery and other protections of the Federal Rules of Civil Procedure. Because of these limitations, Congress explicitly preserved state tort actions as one mechanism for ensuring continued improvement in vaccines.

The compensation system has not lived up to Congress's expectations. HHS, which administers the program, has wrought administrative changes that make it difficult for petitioners to recover for their injuries. Although in the early days of the program, the element of causation was usually presumed, HHS's changes have had shifted the burden of proving causation to the petitioners, who must do so without discovery or many reliable studies of vaccine safety. As a result, vaccine-injured patients are not being compensated for their injuries. These difficulties, coupled with the dearth of information about vaccine safety, render state tort actions a critical safety-valve in the regulatory system. Design defect claims in particular may provide the only incentive to manufacturers to utilize all means at their disposal to create the safest feasible product. Thus, to effectuate Congress's intent to ensure the development of safer vaccines, this Court should conclude that the NCVIA does not preclude design defect claims for products that could have been made safer.

ARGUMENT

I. RESEARCH ON VACCINE SAFETY IS INCOMPLETE

Vaccines are a ubiquitous aspect of American life. All 50 states require that children be vaccinated before entering school.[3] In 1999, 12 million vaccinations were delivered to children every year. *See* U.S. General Accounting Office, *Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily* 4 (1999) (hereinafter "GAO Report"). Vaccination is required for certain occupations, and many other adults also regularly receive vaccines. Institute of Medicine (IOM), *Priorities for a National Vaccine Plan* 53 (Dec. 2009) (hereinafter "*Priorities*"). For example, between two-thirds and three-quarters of the adult population 65 and older received the influenza vaccine in 2008. *See id.*

Over the years, the number of recommended vaccines has increased dramatically. In 1983, children under six received ten inoculations against seven diseases. In 2007, they received thirty-six inoculations against fifteen diseases. *See* Cynthia E.S. Staats & Joel M. Hamme, *The Greater Good: Rethinking Risks and Benefits of Childhood Vaccination Programs*, 3 J. Health & Life Sci. L. 164, 171 (2009). Additional doses are recommended for children aged 7-18 years old. *See* Centers for Disease Control (CDC), *2010 Child &*

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[3] Certain states grant exemptions for religious or philosophical objections, or for health reasons. *See* Institute of Medicine, *Priorities for a National Vaccine Plan* 51 n.2 (2009).

Adolescent Immunization Schedules, at http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm.

Though vaccines are undoubtedly a critical tool to protect populations from disease, "no vaccine is 100 percent effective or 100 percent safe." *Priorities*, *supra*, at 52. For example, the polio vaccine, introduced in the 1950s, caused paralysis in a small number of patients. *See id.* More recently, a vaccine to immunize children against rotavirus, an infection that targets the intestine, was found to cause intussusception, a type of intestinal collapse. *See id.* at 53. The vaccine had been tested in 27 clinical trials involving 10,000 patients before it was licensed in 1998, and no studies either before or immediately after licensure showed an association between the vaccine and intussusception. *See id.* at 55-56. However, as case reports of intussusception trickled in, the CDC ultimately recommended that the vaccine be suspended in 1999. *See id.* at 56. And, as described further below, the Diphtheria, Tetanus, and Pertussis vaccine (DTP)[4] has been associated severe injuries including seizures, brain inflammation, and death.

It is particularly critical to obtain accurate safety profiles for vaccines as compared to other drugs. Not only are they mandatory, but they are also not administered for the purpose of treating a specific ailment. Instead, vaccines are administered to healthy people who are, at most, only at *risk* of contracting a disease. As a result, vaccines must "have a low risk-to-benefit ratio when compared to therapeutic

[4] The DTP vaccine is also known as "DPT."

interventions." *Id.* at 53. The lower the risk of contracting the disease, the lower the acceptable risk level that may be posed by the vaccine. *Id.* at 52 (explaining how the risk-benefit calculation for the polio vaccine changed over time).

It is difficult to perform this necessary risk-benefit calculation because "anticipating, detecting, and quantifying the risks of rare adverse events [from vaccines] presents enormous challenges." *Id.* at 53. Most randomized clinical trials – the "gold standard" for pre-licensure applications, *id.* at 36 – do not have enough participants to detect rare adverse events, *id.* at 53. It is often only possible to detect rare adverse events *after* the vaccine is licensed and distributed to large populations, numbering in the millions. *Id.* Even then, identifying rare adverse events is no easy task. The NCVIA mandated the establishment of the Vaccine Adverse Event Reporting System (VAERS), whereby healthcare providers report to HHS adverse events following inoculation. *See* 42 U.S.C. § 300aa-25. But, like any passive reporting system, VAERS is flawed. It is estimated that only 10% of adverse events are reported. Staats & Hamme, *supra*, at 174.[5] Additionally, without information on the number of persons inoculated, or the

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[5] As an example, the IOM reports that with respect to the rotavirus vaccine, it was discovered that VAERS reporting of intussusception alone (without considering other, less serious, adverse events that may have occurred) only reached 47%. *Priorities*, *supra*, at 56. Among other problems, neither physicians nor patients may recognize an adverse event as associated with the vaccine if there is a delay between administration and the onset of symptoms.

number of persons expected to develop a particular condition without the vaccine, VAERS data is difficult to evaluate. *Priorities*, *supra*, at 57-58. Indeed, HHS has described VAERS data as "anecdotal" and will not rely on it for gauging the dangers posed by vaccines. *See National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table*, 60 Fed. Reg. 7678-01, 7685 (February 8, 1995).

More recent surveillance systems have been developed to detect adverse events associated with vaccines, but these also have weaknesses and/or are underutilized. For example, the Vaccine Safety Datalink (VSD), a joint project of the CDC, the FDA, university researchers, and several health plans, links the data from several health insurers. With its more complete records, it is more reliable and more easily analyzed than VAERS. However, the VSD covers only about 8.8 million people, which still may not be sufficient to detect exceedingly rare events. *Priorities*, *supra*, at 59.

Even with the VSD, critical gaps in our understanding remain. For example, there is no research on whether vulnerable populations, like the elderly or persons suffering from other conditions, have more adverse reactions to certain vaccines. There is no research on whether certain individuals are more susceptible to adverse events, or the effect of the common practice of concurrently administering several vaccines. *Id.* at 66. And a former head of the National Institutes of Health (NIH) points out that the current vaccination schedule – which recommends that all children receive the same dosages of vaccine at the same ages – has not been shown to be optimally safe.

See Bernadine Healy M.D., *A Call for Research on Vaccine Safety*, U.S. News & World Report, Feb. 1, 2009 at 25 (describing a study showing that a slight delay in administering DTP drastically reduced the risk of childhood asthma).

Attempts to accurately assess vaccine safety are hindered by the fact that the National Vaccine Program Office has not updated its National Vaccine Plan since 1994. *See Priorities*, *supra*, at 1. The Plan, required by the NCVIA, is intended to "establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines." 42 U.S.C. § 300aa-3. Even the 1994 Plan "had few measurable objectives and was largely a collection of short-term activities that were . . . scheduled to occur regardless of the National Vaccine Plan." *Priorities*, *supra*, at 139. Thus, functionally, a National Vaccine Plan has never been implemented as required by statute.

The weaknesses in the surveillance system for vaccine safety can be seen in the IOM's reports on specific vaccines. At the request of Congress, the CDC, and the NIH, the IOM has undertaken a series of studies to determine whether commonly-used vaccines are associated with certain serious diseases. *See, e.g.*, IOM, *Immunization Safety Review: Hepatitis B and Demyelinating Neurological Disorders* (Kathleen Stratton et al. eds., 2002); IOM, *Immunization Safety Review: Influenza Vaccines and Neurological Complications* (Kathleen Stratton et al. eds., 2004) (hereinafter "*Influenza Vaccines*"); IOM, *Adverse Effects of Pertussis and Rubella Vaccines* (Christopher

P. Howson et al. eds, 1991) (hereinafter "*Adverse Effects*"). Though the IOM occasionally accepts, or rejects, the hypothesis that a vaccine causes particular diseases, the IOM more commonly concludes that the evidence is insufficient to reach a conclusion either way and more research is required. Thus, the IOM's report on the influenza vaccine stated, "With a vaccine as widely used as influenza vaccine, the committee considers it important to pursue research and research-related activities aimed at ensuring that any risk of GBS [Guillain-Barré syndrome] or other neurological complications is minimized." *Influenza Vaccines*, *supra*, at 14. Dr. Healy similarly opines that "there is scant research on the way the complex networks of specialized white blood cells and immune chemicals behave in response to the currently licensed vaccines and their assorted nonvaccine components. . . . Studies showing that early childhood vaccination may promote chronic allergies, for example, beg for further research." Healy, *supra*; *see also* Committee on Government Reform, *The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices*, H.R. Rep. No. 106-977, at 5 (2000) ("[M]uch remains unknown about possible adverse events that may be associated with past and present vaccination practices"). In sum, vaccine research is "a field bereft of complete and direct proof of how vaccines affect the human body." *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

II. LEGISLATIVE RESPONSE TO CONCERNS ABOUT VACCINE SAFETY

Vaccines are also unique in that they are often administered not as a mechanism for protecting the individual, but as a mechanism for protecting the population as a whole. In *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), this Court held that the States may impose mandatory vaccination in the exercise of their police powers, recognizing that the goal of mass vaccination is not to protect the individual, but to protect the population from outbreaks. *See id.* at 27-28. As the Court put it, "in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand." *Id.* at 29. Today, this concept – known as "herd immunity," i.e., that widespread immunization "lessens the risk that the disease can be introduced and harm members of the community" – is still the main justification for compulsory vaccination. Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 Food & Drug L.J. 351, 359 (2001).

But in service of this goal, individuals must not only sacrifice their liberty, but risk serious injury, as well. It was in recognition of the fact that some members of the public will, necessarily, sacrifice their health – and the health of their children – in service of the greater health of society, that Congress passed the NCVIA.

A. Concerns about DTP Lead to the Passage of the NCVIA

Pertussis, or whooping-cough, is a highly-contagious respiratory infection caused by the *Bordetella pertussis* bacteria. *See Adverse Effects*, *supra*, at 9. The disease causes a spasmodic cough and a high-pitched crowing, or "whoop," from which its name derives. *Id.* The earliest symptoms are similar to those of a minor cold, but over time, the coughing worsens, making it difficult for the patient to breathe and causing vomiting or choking spells and cyanosis. *See id.* at 10. The disease can also damage the central nervous system, resulting in acute encephalitis and cerebral hemorrhage. Long-term, pertussis can cause mental retardation or permanent neurological damage. *Id.* at 11.

Pertussis bacteria secrete a toxin with a variety of effects on the human body. *Id.* at 16. A pertussis vaccine exposes the body to the toxin antigens, thus stimulating the production of antibodies. In DTP, the antigens come from dead "whole-cell" pertussis cells. However, it is difficult to separate the antigens from the toxin, and traces of the toxin may remain, leading to serious side-effects such as vomiting and diarrhea, congestion, high-pitched screaming, collapse, seizures, spasms, loss of muscle control, brain inflammation, diabetes, and death. Scott, *supra*, at 353.

Pertussis vaccine was first created in the early 1900s, *Adverse Effects*, *supra*, at 17, and safety concerns have been raised about DTP since at least as early as the 1930s. Amy Fine, *Diptheria, Tetanus, and Acellular Pertussis Vaccine (DTaP): A Case Study*, Background

Paper Prepared for the Committee on the Evaluation of Vaccine Purchase Financing in the United States, Division of Healthcare Services, IOM at 2 (April 2003), *available at* http://www.iom.edu/~/media/Files/Activity%20Files/Disease/VaccineFinancing/FineBackgroundPaper.ashx. Nonetheless, DTP was one of the earliest combination vaccines licensed by the FDA,[6] and became a staple of pediatric care by the 1940s, where it remained in regular use for the next 50 years. *Id.*

In the 1970s, concerns about DTP's safety began to mount. In Japan and Britain, after widely-publicized cases of infant death following DTP administration, parents refused to immunize their children, resulting in pertussis outbreaks. *Id.* at 3. Japan responded by developing the acellular version of DTP, known as DTaP, which it licensed in 1981. *See* Fine, *supra*, at 7; *Adverse Effects*, *supra*, at 18. DTaP is safer than DTP because rather than using whole cells of the bacteria, it uses only portions of the bacteria and an inactivated form of the toxin. *See* Advisory Committee on Immunization Practices, *Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among Infants and Young Children Recommendations of the Advisory Committee on Immunization Practices* (1997), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00048610.htm.

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[6] Prior to the passage of the 1962 Kefauver-Harris Amendments to the Food, Drug, & Cosmetic Act, the FDA had much more limited ability to test for the safety of new drugs. *See* Katherine A. Helm, *Protecting the Public Health From Outside the Physician's Office*, 18 Fordman Intell. Prop. Media & Ent. L.J. 117, 129 (2007).

In the United States, concerns about DTP reached a tipping point in 1982, when NBC aired the television program "DPT: Vaccine Roulette," reporting on the adverse effects of the DTP vaccine. *See* Lainie Rutkow et al., *Balancing Consumer and Industry Interests in the Public Health: The National Vaccine Injury Compensation Program and Its Influence During the Last Two Decades*, 111 Penn St. L. Rev. 681, 688-89 (2007); Fine, *supra*, at 3. As a result, lawsuits against DTP manufacturers accelerated dramatically, and some manufacturers withdrew from DTP production entirely. Fine, *supra*, at 3. The publicity also resulted in the formation of a parents group known as Dissatisfied Parents Together, which is today known as the National Vaccine Information Center.

In response, Congress held a hearing regarding immunization and preventive medicine, at which the Director of the CDC testified that "a prospective study at UCLA on over 15,000 doses [of DTP] showed nine children with convulsions and nine with episodes of collapse, for a frequency of 1 in 1,750 immunizations for each complication." Rutkow, *supra*, at 689 (quoting *Immunization and Preventive Medicine: Hearing Before the Subcomm. on Investigations and General Oversight of the S. Comm. on Labor and Human Resources*, 97th Cong. 79, at 6 (1982) (testimony of William H. Foege)). By 1984, vaccine compensation bills had been introduced in both houses of Congress, precursors to the NCVIA. *Id.* at 691.

In passing the NCVIA, Congress navigated between parents, who wanted to preserve state tort actions as a mechanism for ensuring vaccine safety, and

manufacturers, backed by the Reagan administration, who sought indemnification from all liability. *Id.* at 693-96. The president of Dissatisfied Parents, for example, testified that only lawsuits can "reveal company negligence and force improvements." *Id.* at 695. Congressman Henry Waxman agreed, stating that Congress should not "assum[e] all the legal risks of immunization programs" and that "[t]his Government should not be in the business of guaranteeing profits to the drug industry." *Id.* at 696. Waxman also insisted that "the tort system [serves] as a constant incentive to regulators and manufacturers alike to keep the vaccine supply as safe as it can be." *Id.* at 698.

The final Act consisted of two parts. In keeping with the emphasis of ensuring safe vaccines, the Act established the National Vaccine Program, housed in HHS, "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C § 300aa-1. The Program empowered its Director to carry out a program of testing for the safety and efficacy of vaccines, and directed the creation of the National Vaccine Plan. *See id.* at §§ 300aa-2(a)(2); 300aa-3. The Program also created the NVAC to guide research priorities. *See id.* at § 300aa-5.

The second part of the act created the National Vaccine Injury Compensation Program (VICP), discussed in more detail below. As parents had requested, and as Congressman Waxman agreed, VICP was a streamlined compensation system that simultaneously preserved state tort remedies. *See id.* at §§ 300aa-10 to -17. This portion of the Act also

emphasized safety; Subpart C, titled "Assuring a Safer Childhood Vaccination Program in the United States," mandated the creation of VAERS, *id.* at § 300aa-25, and directed the Secretary to create a taskforce for the development of safer vaccines, *id.* at § 300aa-27.

Throughout the 1980s, in response to the growing crisis of public confidence and Congress's call for the development of safer vaccines, the NIH sponsored additional research on DTaP. Previously, though industry had developed a technique for making a safer "split-cell" vaccine, it was not marketed because of its costs. *See Graham by Graham v. Wyeth Labs.*, 906 F.2d 1399, 1403 (10th Cir. 1990). NIH now pressured industry to cooperate in DTaP development by making it clear that a switch to DTaP was "inevitable" and that data on DTaP "would be critical to licensure decisions." *Fine, supra*, at 7. The FDA finally licensed Wyeth's DTaP vaccine, Acel-Immune, in 1991 for use as the last two doses in a total series of five administered from infancy through early childhood. *See id.* at 8. Over the next eleven years, the FDA licensed additional DTaP vaccines, produced by different manufacturers, and in 1996 began approving previously-licensed vaccines to cover the first three doses in the series. *See id.* at 9, 15. Today, DTP is no longer used in the United States.

B. Creation of VICP

VICP was created to compensate "vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908 (1986) *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344 (hereinafter "House Report"); *see also id.* at 6353 ("The system is intended

to be expeditious and fair. It is also intended to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective.").

Under VICP, as amended,[7] vaccine-injured persons initially present their petitions to a special master in the Court of Federal Claims specifically employed to handle vaccine injury cases. *See* 42 U.S.C. § 300aa-12. The Secretary of HHS is the respondent. The special master hears evidence and makes a determination of entitlement to compensation, and, if relevant, a damages award. *Id.* at § 300aa-13. The NCVIA specifies the types of harms that may be compensated, and the maximum amount of damages. *See id.* at § 300aa-15(a). Awards are funded with an excise tax, paid by the consumer, imposed on every dose sold of every vaccine included in VICP. *See* 26 U.S.C. § 4131; CDC Vaccine Price List, *available at* http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm (listing current vaccine prices, including the portion attributable to the excise tax).[8]

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[7] Originally, VICP jurisdiction was placed in the federal district courts. The statute was amended in 1987 to transfer jurisdiction to the Court of Federal Claims out of concern that the original design ran afoul of Article III because plaintiffs could reject a judgment and seek state tort remedies. *See* H. Conf. Rep. 100-495, at 771 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1245, at 2313-1517.

[8] A "dose" refers to a dosage that prevents a particular disease; thus, a vaccine that prevents three diseases, such as the measles-mumps-rubella vaccine, counts as three doses. *See http://www.hrsa.gov/vaccinecompensation/VIC_Trust_Fund.htm.*

The monies are held in the Vaccine Injury Compensation Trust Fund ("Trust Fund"). *See* GAO Report, *supra*, at 7.

The Federal Rules of Civil Procedure do not apply to VICP proceedings. 42 U.S.C.A. § 300aa-12. Instead, special masters "provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions" with "flexible and informal standards of admissibility of evidence." *Id.* By statutory command, "[t]here may be no discovery in a proceeding on a petition other than the discovery required by the special master." *Id.*; *see also* Vaccine Rule of the Court of Federal Claims 7 ("There is no discovery as a matter of right. The informal and cooperative exchange of information is the ordinary and preferred practice.").

If the petitioner is unsatisfied with the special master's ruling, the petitioner may appeal to the Federal Circuit. *See* 42 U.S.C. § 300aa-12. Ultimately, if the petitioner is unsatisfied with the final judgment, he or she may reject it and bring an action in state court. *See id.* at §§ 300aa-21(a), 300aa-22. Congress anticipated that vaccine injury claims would be heard "within strict time limits, subject to similarly expeditious review." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) (citing §§ 300aa-12(d)(3)(A); 300aa-12(e)(2)).

The centerpiece of VICP is the Vaccine Injury Table. The Table, originally mandated in 42 U.S.C. § 300aa-14(a), lists vaccines covered by the program, their associated injuries, and expected onset times. The Table is accompanied by Qualifications and Aids to Interpretation (QAI) that further define the Table

injuries. *See id.* § 300aa-14(b). If the petitioner received a vaccine listed on the Table, and experienced a Table injury, causation is presumed, subject to a right of rebuttal by the Secretary. *See id.* at §§ 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(B). If the petitioner did not receive a Table injury, it is the petitioner's burden in the first instance to establish causation. *See id.* at § 300aa-11(c)(1)(C)(ii). "Thus, the content of the Table . . . is critical: it is only when a vaccinated child suffers a listed condition within applicable temporal parameters that compensation will be forthcoming without the time, expense, proof requirements, and uncertainty of full-blown litigation." *O'Connell v. Shalala*, 79 F.3d 170, 173 (1st Cir. 1996).[9]

Because Congress recognized that eventually "research on vaccine injury and vaccine safety" would provide "more definitive information about the incidence of vaccine injury," House Report, *supra*, at 6359, the Secretary may promulgate regulations that add to, or delete, the injuries listed on the Table, or alter the onset time periods. *See* 42 U.S.C. § 300aa-14(c)(3). Such revisions are made through ordinary notice and comment procedures. *Id.* § 300aa-14(c)(1).[10] To assist the

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[9] Vaccines not listed on the Table are not included in VICP; persons injured by those vaccines may bring ordinary tort actions. *See* 42 U.S.C. § 300aa-33 (defining "vaccine-related injury or death" to mean injuries associated with Table vaccines).

[10] In 1999, the Federal Circuit rejected a constitutional challenge to the Secretary's ability to make administrative changes to the statutory Table. *See Terran v. Sec'y of HHS*, 195 F.3d 1302 (Fed. Cir. 1999).

Secretary in this effort, Congress created the ACCV, composed of nine members appointed by the Secretary. *Id.* § 300aa-19. The members must include three non-governmental health care professionals with relevant experience, three members of the general public (at least two of whom have vaccine-injured children), and three attorneys (two of whom are experienced, respectively, in prosecuting and defending vaccine claims). *Id.* The ACCV advises the Secretary in the implementation of the National Vaccine Program, and recommends changes to the Table. *Id.* Any of the Secretary's proposed changes to the Table must first be reviewed by ACCV. *Id.* § 300aa-14(d).

Congress never intended that VICP would replace state tort law or its deterrent functions; instead, VICP was created in the hope that its simplicity and speed would lure some plaintiffs away from state tort litigation by choice, rather than legislative fiat. *See* House Report, *supra*, at 6354 ("The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation."). This goal rested on Congress's prediction that most vaccine petitions would concern on-Table injuries. *See id.* at 6353 (VICP is "intended to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury. . . ."). Professor Timothy Westmoreland, who served as Counsel to the Subcommittee on Health and the Environment in the House of Representatives at the time of the NCVIA's passage, characterized the Table as the "perceived giant

step" of VICP. In his view, provisions for off-Table injuries were merely an "afterthought" or a "safety-valve" in a system expected to be dominated by Table injuries. Seventeenth Judicial Conference of the United States Court of Federal Claims (2004) Tr. 25:25 to 26:25 (hereinafter "2004 Judicial Conference"), *available at* http://www.uscfc.uscourts.gov/sites/default/files/Judicial%20Conference%20transcript.pdf.

It is for this reason that Congress mandated restricted discovery and informal procedures during VICP proceedings: "Because the only issues relevant to the compensation proceeding are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages, there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues." House Report, *supra*, at 6357. Thus, when the Vaccine Court discovery rules were drafted in 1988 and 1989, they were "geared more towards the table cases" and were not designed to handle the burdens of off-Table cases. 2004 Judicial Conference, Chief Special Master Golkeiewicz of the Court of Federal Claims, Tr. 97:9-10.

III. VICP IN PRACTICE

Until 1995, 74% of vaccine cases concerned on-Table petitions. *See* GAO Report, *supra*, at 14. However, the tide shifted due to three changes to the operation of VICP.

First, in 1993, Congress amended the statute to require the Secretary to add to the Table all vaccines recommended by the CDC for routine administration

to children, thus including them in VICP. *See* Omnibus Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 646 (1993) § 13632; 42 U.S.C. § 300aa-14(e)(1)[11]; *see also* Vaccine Injury Table, ftp://ftp.hrsa.gov/vaccine compensation/vaccineinjurytable.pdf (listing "Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children" and identifying vaccines added pursuant to this provision). However, in making these additions, the Secretary did not associate any injuries with these vaccines. Thus, any person claiming to be injured by these vaccines necessarily must bring an off-Table petition, with the attendant burdens of proof. Eight vaccines are now on the table with no associated injuries.[12]

Additionally, in 1995 and 1997, the Secretary promulgated new regulations that removed many common injuries, and altered the QAI to narrow the definitions of others. As the GAO concluded,

> [M]ore claims were associated with the injuries removed from the table than were associated with the injuries that were added.

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[11] New vaccines may only be added to the Table under this category after Congress votes to impose the excise tax. *See* Pub. L. No. 103-66, Title XIII, Ch 2, Subch B, Part IV, § 13632(a)(3), 107 Stat. 646.

[12] One vaccine, Hepatitis B, was added with only a single associated injury – anaphylaxis – despite the "ongoing concern that rheumatoid arthritis and other autoimmune conditions have been triggered by the hepatitis B vaccine in those with genetic susceptibility." Healy, *supra*,

> Significantly, . . . about 45 percent (611) of the 1,368 claims awarded compensation under VICP were for injuries subsequently removed from the table. These claims accounted for about half of the $974 million awarded thus far under the program.

GAO Report, *supra*, at 14. By 1999, only 55% of petitions were on-Table. *See id.*; *see also* 2004 Judicial Conference Tr. 60:5 to 60:24 (Judge Abell, noting that since the Table alterations, the vast majority of cases are brought off-Table). The VICP Strategic Plan, prepared by the Division of Vaccine Injury Compensation within HHS ("DVIC"), confirms that one "critical issue" facing VICP includes the "dramatic shift in claims from nearly all alleging a Vaccine Injury Table condition to the majority now alleging a non-Table condition, which creates a more difficult burden for petitioners." DVIC, *National Vaccine Injury Compensation Program Strategic Plan*, at 1 (April 2006) (hereinafter "Strategic Plan"), *available at* ftp://ftp.hrsa.gov/vaccinecompensation/strategic_Plan_20060411.pdf. Chief Special Master Golkiewicz reported that as of 2001, he had "yet to adjudicate a case involving the interpretation of the amended Table; all litigated claims have been causation cases." *Stevens v. Sec'y of HHS*, No. 99-594V, 2001 WL 387418, at *8 (Fed. Cl. Mar. 30, 2001), *abrogated on other grounds by Althen*, 418 F.3d at 1274.

These alterations to the Table were ostensibly made, in part, in reliance on newer studies conducted by the IOM. As described above, Congress anticipated that the development of scientific understanding of vaccines would result in changes to the Table. *See* House Report,

supra, at 6359. Thus, the NCVIA directed the IOM to examine the medical evidence associating vaccines with particular injuries in order to assist HHS with Table revisions. *See* 42 U.S.C. § 300aa-1 note. These reviews were conducted in 1991 and 1994. *See* GAO Report, *supra*, at 13.

However, many of the administrative changes were at odds with the IOM's findings. For example, despite the IOM's finding of evidence of a causal relationship between tetanus and oral polio vaccines and Guillain-Barré syndrome, HHS did not add this injury to the table. GAO Report, *supra*, at 15. The GAO ultimately concluded that "establishing a clearly defined, transparent decisionmaking process [for Table revisions] is important to help advance the appearance of fairness. HHS has not produced such a methodology, and its actions do not always convey a sense of consistency." *Id.*[13]

Several of the 1995 Table revisions concerned the injuries associated with DTP. In particular, the revisions deleted "residual seizure disorder" and "hypotonic, hyporesponsive episodes" as compensable DTP injuries. *See* 60 Fed. Reg. at 7694-95. Moreover, after first proposing that encephalopathy be deleted as a compensable injury associated with DTP, the Secretary ultimately chose to significantly narrow the definition of encephalopathy in the QAI. *See O'Connell*, 79 F.3d at

[13] The IOM concluded that for seventy-five percent of the conditions studied, there was insufficient evidence to either accept or reject a causal connection, thus leaving the state of medical knowledge with respect to those vaccines largely unchanged from 1986, when the first Table was created by statute. *See* GAO Report, *supra*, at 13.

174-75. These changes were made despite the IOM's conclusion in 1991 that there existed a causal relationship between DTP and "acute encephalopathy and hypotonic, hyporesponse episodes," and the IOM's subsequent conclusion in 1994 that there existed a causal relationship between DTP and certain chronic nervous system dysfunctions. *Id.* at 174. As a result of the 1995 changes, the Table definition of encephalopathy is:

> more restrictive than that of the leading epidemiological study of pertussis vaccine injury, the British National Childhood Encephalopathy Study (NCES). Moreover, seizures have been removed from the Table, although that the pertussis vaccine can cause seizures is uncontested (and warned in the manufacturer's package insert), and although the NCES found a significant association between a severe seizure and DPT administration in the preceding three days (a finding that was endorsed by the Institute of Medicine).

"Compensating Vaccine Injuries: Are Reforms Needed?": Hearing Before the Subcomm. on Criminal Justice, Drug Policy and Human Res., Comm. on Gov't Reform (1999) (testimony of Marcel Kinsbourne, Pediatric Neurologist). Today, the Table associates DTP only with encephalopathy (using the narrowed definition) and anaphylaxis. *See* Vaccine Injury Table, *supra.*[14]

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[14] In this case, for example, Hannah Bruesewitz's injuries likely would have been considered on-Table but for the 1995 administrative revisions. *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 237 n.5 (3d Cir. 2009).

Without recourse to the Table, vaccine-injured patients do not receive the benefit of the bargain originally struck by VICP, whereby the "equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment." House Report, *supra*, at 6358. Petitioners report that VICP has become extremely adversarial, with veteran full-time litigators from the Justice Department fighting over "minutia like the future cost of diapers in a certain state." Scott, *supra*, at 362; *see also* GAO Report, *supra*, at 10 (HHS has "established an expert witness program" to challenge claims); Katherine E. Strong, Note, *Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day*, 75 Geo. Wash. L. Rev. 426, 446-47 (2007).[15] The bars on discovery, coupled with the dearth of medical knowledge about vaccine safety, aggravates the plight of petitioners by making it even harder for them to prove that their injuries were caused by vaccines by a preponderance of evidence, as the NCVIA requires. 42 U.S.C. § 300aa-13(a)(1). As described above, evidence from VAERS is not accepted by the HHS. Moreover, petitioners are not granted access to the VSD. *See, e.g.*, *In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder*, 2007 WL 1983780 (Fed. Cl. May 25,

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[15] In the words of one special master, HHS's counsel was "abrasive, tenacious, obstreperous litigation tactics were inappropriate in a program that is intended to be less adversarial; and hindered greatly a fair, expeditious resolution of the case. In addition, counsel lacks simply tact and compassion. Quite frankly; the special master is embarrassed that respondent's counsel and respondent's life care planner represented the United States Government in this case." H.R. Rep. No. 106-977 at 13.

2007). Similarly, requests from petitioners to obtain discovery from manufacturers, who are not parties to VICP proceedings, are routinely denied. *See, e.g.*, Published Ruling Quashing Subpoena, *Deloatch v. Sec'y of HHS*, No. 1:09-vv-00171-UNJ (Fed. Cl. Apr. 27, 2010). As a result, "Even though the same vaccines and injuries are represented in the cases, clear answers have proven elusive to the numerous causation-in-fact issues presented over the twelve year history of the Program." *Stevens*, 2001 WL 387418, at *7.

Moreover, contrary to Congress's intent, VICP proceedings are anything but "expeditious," often taking years to resolve. *See* GAO Report, *supra*, at 20-21; Strategic Plan, *supra*, at 8; Scott, *supra*, at 358. Chief Special Master Golkiewicz agrees: "[L]itigating causation cases has proven the antithesis of Congress's desire for the Program. Instead of speed, certainty, and fairness, costly lengthy case presentations, inconsistent outcomes, and disparate treatment of similarly-situated litigants has resulted." *Stevens*, 2001 WL 387418, at *7.

The proof is in the pudding: with so many claims involving difficult-to-prove off-Table injuries, only one-third of petitioners receive VICP compensation. *See* Brief of the United States as Amicus Curiae, *Am. Home Prods. Corp. et al. v. Ferrari et al.*, No. 08-1120, at 4 (Jan. 29, 2010). Correspondingly, the Trust Fund has become engorged, holding over $3.2 billion as of April 30, 2010, as compared to $1.3 billion at the end of 1998. *Compare* ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0410.pdf *with* GAO Report, *supra*, at 16.[16] This

[16] The Fund has exceeded Congressional Budget Office projected growth rates. *See* H.R. Rep. No. 106-977, at 14.

figure far exceeds the amount expected to pay claims. *See* GAO Report, *supra*, at 18.[17]

HHS has demonstrated a marked reluctance to expand and update the injuries on the Table. For example, HHS rejected an ACCV recommendation in April 2005 to add to the Table certain injuries associated with the varicella and hepatitis A vaccines. *See* Letter to Secretary Michael O. Leavitt from Don L. Wilber, M.D., Chair of the ACCV (April 19, 2005).[18] Instead, HHS lists both vaccines on the Table without any associated injuries. *See* Vaccine Injury Table, *supra*.

HHS also refuses to use VAERS data as a basis for updating the Table. *See* 60 Fed. Reg. at 7685. The IOM reports that although vaccine cases could provide a valuable source of information regarding the association of vaccines with particular injuries, they are not used to formulate hypotheses for testing in the VSD. *See Priorities*, *supra*, at 65. Dr. Geoffrey Evans, Medical Director of DVIC, explains that HHS is more "reactive" than "proactive" in altering the Table:

> This is something that if HRSA [the HHS Health Resources and Services

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[17] The Strategic Plan concludes that the size of the fund is necessary and appropriate given the need for risk reserves. *See* Strategic Plan, *supra*, at 28. The GAO disagrees. *See* GAO Report, *supra*, at 18.

[18] The ACCV recommendations were based on a DVIC presentation at a March 2005 meeting regarding injuries associated with the varicella and hepatitis A vaccines. *See* ACCV Work Group Meeting Minutes, March 9, 2005.

> Administration] had the extra resources it would have been nice if we did have timely reviews of the vaccine injury table all along. . . . But it is something that is not practical. There are not a lot of things that are done in government today that are proactive. They are more reactive and this would be one of the more important proactive things to do, but there is probably a whole long line of people with proactive things that they would like to see done for the program.

HHS, ACCV Conference (March 9, 2006), Tr. 103 (hereinafter "2006 ACCV Conference").

HHS's reluctance to update the Table with new injuries apparently stems, at least in part, from the fear that if vaccines are publicly linked with injuries on the Table, the negative association will dissuade people from seeking inoculation. A report issued by the House of Representatives' Committee on Governmental Reform notes that there is an inherent conflict in the dual roles of HHS in encouraging drug development and vaccination on the one hand, and administering VICP on the other. *See* H.R. Rep. No. 106-977, at 16. In the Strategic Plan, DVIC concludes, "Relaxed standards for assessing causation of vaccine-related injury could jeopardize the public's trust of, and reliance upon, vaccines. . . . The relaxed standard may lead to more claims being compensated; and therefore, the public may think that vaccines are not safe." *See* Strategic Plan,

supra, at 27.[19] Similarly, Dr. Evans, speaking at the Nineteenth Judicial Conference of the United States Court of Federal Claims in 2006 (hereinafter "2006 Judicial Conference"), *available at* http://www.uscfc.uscourts.gov/sites/default/files/061025.pdf stated:

> I want to at least put my public health hat on for a moment and address one of the ideas that was put forward, and that was that you could just simply add injuries to the vaccine injury table. . . . [T]here are statutory provisions tied to the table, such as the vaccine information statements[20] and the VAERS program . . . so that if we do add lots of different injuries to them, then it's going to have some public health consequences. This program doesn't really operate with the outside interest of what is going on in the public sector as much as one would think.

2006 Judicial Conference Tr. 111:15-112:3.[21] Notably, Congress heard this same objection from HHS when it considered the program – and, by enacting VICP,

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[19] *See also* Strategic Plan, *supra*, at 25 ("The very existence of the VICP communicates a mixed message that while vaccines are beneficial and safe, they may, in rare instances, cause injury or death.").

[20] Vaccine information statements, stating the risks and benefits of a vaccine, are required to be distributed to parents under the NCVIA. *See* 42 U.S.C. § 300aa-26.

[21] Though the transcript attributes the comment to an unidentified "male voice," Ms. Willner attended the conference and confirms that Dr. Evans was speaking.

apparently rejected it. *See* Rutkow, *supra*, at 692 (quoting the Assistant Secretary of HHS, testifying before a congressional committee in 1984, as objecting to the Table on the grounds that it created "a strong presumption that vaccine[s] [are] responsible for essentially any adverse condition that happens after immunization unless there is incontrovertible evidence of other causation").

As a result of this dual system – whereby new vaccines are added to the Table, but HHS does not add associated injuries – almost all persons suffering vaccine injuries must bring their claims through VICP,[22] and every injury is litigated in a full-blown adversarial proceeding without the protections of the Federal Rules of Civil Procedure. Chief Special Master Golkiewicz points out:

> The acuteness of the problem is seen with newly added vaccines, such as the hepatitis B vaccine which was added to the Program in August of 1997. These vaccines are being added without the benefit of a multi-injury Table. Thus, practice has shown that virtually all of the cases proceed as causation-in-fact disputes. In fact, all 267 pending hepatitis B cases are causation claims.

Stevens, 2001 WL 387418, at *8. As the IOM recently concluded, "[t]here have been delays in updating injuries

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[22] *See* Dr. Evans, 2006 ACCV Conference Tr. 51 ("[R]ight now we are covering 95 percent of vaccines distributed in this country. . . . So we are very close to covering all of the vaccines."); CDC Vaccine Price List, *supra* (listing prices for each vaccine, including the portion attributable to the VICP excise tax).

listed in the table and undertaking the necessary research to update the table. This has generated concern that there is a lack of government commitment to understanding the full extent of vaccine risks even as it pursues universal immunization as a public good." *Priorities*, *supra*, at 63. The system has thus diverged from Congress's original design: "[W]ithout such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner." House Report, *supra*, at 6358.

IV. THE IMPORTANCE OF STATE TORT REMEDIES

Within this context, the availability of state tort actions takes on critical significance. In creating VICP, Congress expressed a preference for offering vaccine-injured parents the "carrot" of quick compensation rather than the "stick" of preemption. *See* House Report, *supra*, at 6354 (recognizing that the benefits of VICP will "divert a significant number of potential plaintiffs from litigation"). VICP, with its no-fault structure, functions as an alternative to strict liability under state tort law. But Congress never intended either VICP or the NCVIA to replace state tort law with respect to substantive protections that states provide their citizens.

For example, the NCVIA could have, but did not, preempt failure-to-warn claims based on FDA-approved labeling. Instead, the NCVIA eliminated strict liability and imposed a higher burden of proof. *See* 42 U.S.C. § 300aa-22(b)(2). In this manner, Congress preserved the standards of conduct imposed by states while ensuring that vaccine manufacturers are protected

against excessive liability. Similarly, Congress did not eliminate claims based on a failure to properly prepare the vaccine, *see* 42 U.S.C. § 300aa-22(b)(1), despite heavy FDA regulation of manufacturing, *see* 21 C.F.R. § 312.23(a)(7); 21 C.F.R. Pts 210 & 211.

With respect to state law claims based on the failure to warn patients directly of the risks associated with vaccines, Congress legislatively adopted the learned-intermediary doctrine. 42 U.S.C. § 300aa-22(c); *see also Reyes v. Wyeth Labs*, 498 F.2d 1264, 1276 (5th Cir. 1974) (prior to the enactment of NCVIA, refusing to apply the learned intermediary doctrine to mass vaccination). At the same time, Congress required that all patients personally receive an information statement explaining the vaccine's risks and benefits. 42 U.S.C. § 300aa-26. Once again, though Congress eliminated a source of liability, it preserved the substantive protections of state law.

Read in this light, it is plain that when Congress preempted claims concerning "unavoidably unsafe" vaccines, it did not intend to eliminate state-imposed legal requirements without providing an effective replacement. Nothing in VICP, or in any federal regulation, requires that manufacturers develop the safest feasible design when manufacturing their products. At best, VICP is a substitute for design-defect claims where there is no safer alternative – i.e., compensation for patients who, as the necessary price of ensuring the public health, personally bear the burdens of compulsory vaccination. But Congress never intended that VICP would replace the important deterrent functions of state tort law in spurring

manufacturers to design safer products; indeed, due to the restricted discovery available in VICP proceedings, as well as the dearth of research regarding the adverse effects of vaccines and the difficulties in conducting such research, state tort actions remain a critical mechanism for realizing Congress's goal of "promot[ing] the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market." 42 U.S.C. § 300aa-27(a)(1).

It is indisputable that state damages litigation "may aid in the exposure of new dangers associated with" a product. *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 451 (2005). This is because "[t]he information-gathering tools lawyers have in litigation are, by any measure, more extensive than the FDA's." David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Effort to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461, 492 (2008). Plaintiffs frequently use the discovery process to uncover evidence that manufacturers are aware of risks unknown to regulatory authorities. *See id.* at 492-95; *see also* Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 309 (2007); Peter D. Jacobson & Kenneth E. Warner, *Litigation and Public Health Policy Making: The Case of Tobacco Control*, 24 J. Health Pol. Pol'y & L. 769, 788 (1999). In turn, these discoveries prompt government regulators to take action. *See* Kesselheim & Avorn, *supra*, at 310; Jacobson & Warner, *supra*, at 788-89.

Nor is it sufficient that federal agencies examine new vaccine applications and conduct post-market surveillance. Even for ordinary drugs, "pre-approval

testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies (for example, the elderly, ethnic minorities, and pregnant women)." Kessler & Vladeck, *supra*, at 471. After approval, "the FDA's information-gathering power is more limited. . . . [C]ompanies have no obligation to provide the FDA with the company's evaluations of the drug's performance in the market." *Id.* at 491-92.

The problem is particularly acute for vaccines because they are so widely distributed to people of varying ages or with greater or lesser health vulnerabilities. During the pre-licensure examination – when FDA scrutiny is at its zenith – there will not be a sufficiently large or diverse pool of patients to permit a full evaluation of the vaccine's safety profile. *Priorities*, *supra*, at 53. Only after the vaccine has been distributed to millions of people may safety problems become detectable to outside observers, and even then, the information available to regulators may be difficult to interpret.

Therefore, Congress's mandate for the development of safer vaccines will be critically hobbled if plaintiffs are not permitted to bring claims in state courts alleging that manufacturers could have designed safer products. With the abilities of government agencies so limited, and the scope of VICP determinations so narrow, state tort actions are indispensable mechanism of information-gathering in a field characterized by inherent difficulties in conducting research. Design defect claims in particular may provide the only incentive that

manufacturers have to utilize all means at their disposal to manufacture the safest feasible product. Given Congress's recognition of the importance of tort law, it is unreasonable to think that Congress directed the inclusion of virtually all vaccines on the Table, including the newest vaccines about which the least is known, without also intending to preserve the "constant incentive to regulators and manufacturers" of the state tort system to ensure that manufacturers continue to develop safer products. Rutkow, *supra*, at 698.[23]

In its *Ferrari* amicus brief, the United States argued that local juries may misunderstand the careful "cost/benefit calculus" that requires a trade-off of individual safety relative to the public good. U.S. Br. at 15. But nothing in Petitioners' argument displaces the role of federal regulators in conducting this cost/benefit analysis, because HHS has complete control over VICP. If HHS believes that the benefits of a drug are worth its costs to the public, it can list associated injuries on the Table and thereby "divert a significant number of potential plaintiffs from litigation as Congress intended. House Report, *supra*, at 6354.[24] But if HHS chooses to

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[23] That Congress did not see VICP as a substitute for the incentives provided through state tort law can be seen in the evolution of the excise tax. Originally, the tax was imposed on a risk-adjusted basis, with a higher tax for vaccines that caused the most injuries; in 1997, Congress amended the statute to provide a flat seventy-five cent tax on all doses. See GAO Report, *supra*, at 7 n.9. Thus, Congress made it clear that VICP is not part of the regulatory mechanism for incentivizing manufacturers to adopt safer vaccine designs.

[24] But for the 1995 table revisions, Petitioners in this case likely would have received VICP compensation and foregone a state lawsuit.

eliminate injuries from the Table and create virtually insurmountable barriers to petitioners proceeding through VICP, Congress has mandated that state tort law fill the gap. *See* House Report, *supra*, at 6358 (noting the "injustice" of eliminating state tort remedies without providing effective VICP compensation). Such an interpretation is supported by the NCVIA legislative history, where Congress recognized the importance that state tort law plays in spurring both manufacturers *and regulators* to create safer products. Rutkow, *supra*, at 698.

Moreover, as a practical matter, government agencies need access to the kind of information that only tort actions can provide to perform their own "cost/benefit calculus." And although the United States suggests that blanket protection from all design defect liability is necessary to shield fragile vaccine manufacturers from industry-destroying liabilities, U.S. Br. at 20, in fact, the IOM reports that today, vaccine manufacturing "appears increasingly promising for the industry, as demonstrated by the expansion of in the number of manufacturers, a promising pipeline of new vaccines, and a changing view of the profitability of vaccines." *Priorities*, *supra*, at 32.[25] Thus, the additional protections that the United States seeks to bestow are not necessary to preserve the field.[26]

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[25] Pfizer recently purchased Wyeth in part to enter the vaccine market by obtaining rights to Prevnar, Wyeth's children's pneumonia vaccine. *See, e.g.*, Pfizer 2008 Annual Review at 7, *available at* http://www.pfizer.com/investors/financial_reports/annual_reports/pfizer_wyeth.jsp.

[26] There is reason to doubt that relief from liability plays much of a role in manufacturing decisions today. For example, (Cont'd)

CONCLUSION

For the reasons stated above, the NCVIA should not be interpreted to preempt all design defect claims.

Respectfully submitted,

ANN M. LIPTON
Counsel of Record

SALVATORE J. GRAZIANO
BERNSTEIN LITOWITZ BERGER
& GROSSMANN LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 554-1400
ann@blbglaw.com

Counsel to Amicus Curiae
Marguerite Willner

(Cont'd)

in 2004, Congress voted to impose an excise tax on the influenza vaccine (thereby adding it to the Table) out of concern that fear of liability was driving manufacturers from the market. Such relief from liability did not increase influenza vaccine production. *See* Rutkow, *supra*, at 721-24.